

WILMINGTON RODNEY SQUARE

**NEW YORK** ROCKEFELLER CENTER

Attorneys at Law

March 8, 2019

#### BY E-FILE AND HAND DELIVERY

**REDACTED - PUBLIC VERSION** 

The Honorable Colm F. Connolly United States District Court of Delaware 844 North King Street Wilmington, DE 19801

Re: Genentech, Inc. v. Amgen Inc., C.A. No.: 17-1407-CFC (Consolidated)

Defendant Amgen Inc. respectfully submits this letter brief seeking the following relief:

I. Amgen seeks an order compelling Plaintiffs to produce, within one week, biosimilar-related licenses or settlement agreements to the asserted patents.

Despite agreeing to do so on May 14, 2018 (Ex. 1 (Response to RFP No. 63)), Plaintiffs still have not produced these documents, which are indisputably relevant to the determination of a reasonable royalty. Plaintiffs tried to excuse their non-production by arguing that all of the third party signatories object to Genentech's production. This is not a valid excuse. Confidentiality restrictions in license agreements cannot bar their production. The parties carefully negotiated and agreed to a one-tier protective order, which Plaintiffs expressly acknowledged would adequately protect the confidentiality of these materials, if Plaintiffs could redact the names of the third parties—an agreement Judge Sleet recognized. 2018-07-11 Hr'g Tr., at 31:3-32:3 (Ex. 2 (Excerpted)). There is no need for special treatment now.

II. Amgen seeks an order compelling Plaintiffs to produce, within one week, documents from a Genentech biosimilar litigation<sup>2</sup> (the "Celltrion Case") involving one of the patents asserted here (U.S. Patent No. 8,574,869 ("Kao")) and the same validity and claim construction issues currently being litigated in this case.

Despite agreeing to produce these documents on October 30, 2018 (Ex. 3, at 6), Genentech still has not done so. Since then, Amgen has followed up with Plaintiffs at least four times on the status of their production. Ex. 4, at 1; Ex. 5, at 4; Ex. 6, at 2-3; Ex. 7, at 2. Genentech repeatedly represented that the documents would be forthcoming. *Id.* 

<sup>&</sup>lt;sup>1</sup> See, e.g., Wyeth v. Orgenus Pharma Inc., 2010 WL 4117157, at \* 4 (D.N.J. Oct. 19, 2010) (overruling objection to producing license due to third party confidentiality concerns, finding "courts have routinely recognized that license agreements relating to the patent-in-suit... are discoverable and that Plaintiffs' third party confidentiality concerns do not outweigh legitimate grounds to compel production.") (collecting cases).

<sup>&</sup>lt;sup>2</sup> Genentech, Inc. et al. v. Celltrion, Inc. et al., C.A. Nos. 18-00574 and 18-11553 (D.N.J.).

The Honorable Colm F. Connolly Page 2

During the January 23 deposition of Plaintiffs' expert, Dr. Hauser—who opines here on the construction of the term "following fermentation" in Kao (D.I. 270)—Amgen learned that Dr. Hauser also offered opinions and testimony in the Celltrion Case on the very same issue. Dr. Hauser confirmed that none of his opinions regarding validity or claim construction contained confidential information. Ex. 8, Hauser Dep. (Excerpt), at 23-24. Thereafter, Amgen again requested the materials, explaining the prejudice caused by Plaintiffs' failure to produce them before the deposition. Ex. 9, at 1. Plaintiffs then produced three unhelpful documents: the fully redacted deposition transcripts of two experts, Dr. Hauser (Ex. 10) and Dr. Robinson (Ex. 11), and a declaration of another expert, with only a partial discussion of Dr. Hauser's opinions (Ex. 12, at ¶167-179). Plaintiffs claim that they cannot produce more because Celltrion—whose blanket redactions were vastly overbroad—has not allowed it.

Genentech, as the opposing party in the Celltrion Case, should have challenged Celltrion's redactions (Ex. 13, at 11 (§IV)), but has not done so over the last four months. Although Celltrion represented on March 7 that it would produce additional materials in the coming weeks, it has made similar claims in the past and failed to follow through on them. Amgen has invited Genentech to inform Celltrion of this motion to compel, if it wished to intervene.

III. Amgen seeks an order compelling Plaintiffs, within one week, to (i) identify relevant witnesses in response to Amgen's Interrogatories, and (ii) fully respond to Amgen's Interrogatory No. 8, seeking claim charts mapping Avastin® to the asserted claims.

Plaintiffs refuse to disclose the identity of specific witnesses in response to Amgen's interrogatories. Instead, Plaintiffs non-responsively refer only to broad swaths of people—"Plaintiffs' fact witnesses, . . . the inventors, . . . and Plaintiffs' expert witnesses". Ex. 14, at 36. Plaintiffs argue that Amgen's interrogatories "improperly seek[] attorney work product" (Ex. 15, at 2), a position that lacks credibility because Plaintiffs' initial disclosures are similarly flawed. Ex. 16, at 2-6 (listing inventors, two individuals, and "current and former employees").

Plaintiffs should not be permitted to evade their discovery obligations by hiding the identity of relevant witnesses. Amgen raised this concern at the October 10, 2018 hearing when Plaintiffs refused to identify email custodians on issues other than damages. The Court then warned Plaintiffs of the consequences of "play[ing] games" with their witnesses. Oct. 10, 2018 Hr'g Tr., at 138:8-140:19 (Ex. 17 (Excerpt)). With only four months remaining in fact discovery, Plaintiffs' tactics prejudice Amgen's ability to participate in discovery and take depositions.



IV. Amgen seeks an order compelling Plaintiffs to produce factual data derived from testing of Amgen samples, on which Plaintiffs relied to narrow the asserted claims.

Plaintiffs demanded that Amgen provide samples to facilitate narrowing the asserted claims. Oct. 10, 2018 Hr'g Tr., at 82:8-18 (Ex. 17 (Excerpt)). The Court, in response to Plaintiffs' claim of need, ordered the production of samples, and required Genentech to "narrow the number of claims once this information is put in Genentech's hand." *Id.* at 109:18-110:12.

The Honorable Colm F. Connolly Page 3

After receiving the samples, Plaintiffs narrowed the asserted claims, stating "Genentech's selection of claims is informed by Amgen's production of samples . . . ." Ex. 18, at 2. Because Plaintiffs relied on the samples, Amgen requested production of the test results. Plaintiffs refused, arguing the information is privileged and attorney work product. Ex. 19, at 1. Plaintiffs, who bear the burden to show the information is protected, cannot withhold this purely factual information. Even if it was once protected work product, that protection is overcome by Amgen's need for the data because (i) Plaintiffs relied on it to narrow the claims, (ii) the documents admittedly "contain operative facts relevant to issues" given Plaintiffs' representations to the Court; and (iii) Amgen has no other mechanism to obtain this discovery.

V. Amgen and a third party who Amgen's counsel represents, Angela Stambaugh, seek a protective order and an order modifying or quashing three deposition subpoenas.

On February 25, 2019, Plaintiffs served revised deposition notices directed to three individuals—two of whom are current Amgen employees, and one of whom recently left the company, Angela Stambaugh. Ex. 20. The next day, Plaintiffs served deposition subpoenas on the same individuals. D.I. 276. Both the notices and subpoenas would have commenced the first deposition on March 6—providing only 9 days' notice<sup>5</sup>—with the other two depositions noticed for March 7 and March 8. Ex. 20; D.I. 276. Plaintiffs stated that they "remain amenable to scheduling these depositions at alternative dates and locations . . . ." Ex. 21.

Amgen, in response, identified available dates for the witnesses and offered them to opposing counsel. Ex. 22 (offering dates in May 2019—two months prior to the fact discovery cut-off). Plaintiffs rejected Amgen's dates, and insisted that the depositions begin in March, or else Plaintiffs would expect the witnesses to appear on the noticed dates. Ex. 23. Amgen agreed to attempt to find alternative dates and is in the process of doing so, but unfortunately is required to file this motion for a protective order and to modify or quash the subpoenas given Plaintiffs' threat of enforcing the original noticed dates. The court should grant Amgen's and Angela Stambaugh's motion to allow the parties to continue their discussions.

<sup>&</sup>lt;sup>3</sup> Pfizer Inc. et al. v. Lupin Pharms., Inc., et al., 2013 WL 6247357, at \*2 (D. Del. Dec. 2, 2013).

<sup>&</sup>lt;sup>4</sup> Sandvik Intellectual Property AB v. Kennametal, Inc., 2011 WL 466696, at \*2-\*4 (W.D. Pa. Feb. 4, 2011) (ordering production of internal testing made in anticipation of litigation upon showing of substantial need—namely, that "the documents contain operative facts relevant to issues involved in the present litigation—because "Kennemetal may not withhold such information that is merely factual under the umbrella of the work product doctrine."); Union Carbide Corp. v. Dow Chem. Co., 619 F. Supp. 1036, 1051 (D. Del. 1985) (ordering production of "purely factual recitations of technical data" and overruling objection based on "[t]he fact that the documents were prepared by or forwarded to [] in-house counsel").

<sup>&</sup>lt;sup>5</sup> This 9-day notice period is presumptively unreasonable under Local Rule 30.1, which provides "reasonable notice' for the taking of depositions . . . shall not be less than 10 days." Under Fed. R. Civ. P. 45(d)(3)(A)(i), the Court should quash or modify the subpoenas because they "fail[] to allow a reasonable time to comply."

The Honorable Colm F. Connolly Page 4

Respectfully,

/s/ Melanie K. Sharp

Melanie K. Sharp (No. 2501)

MKS

cc: Michael P. Kelly, Esquire (by e-mail)

Daniel M. Silver, Esquire (by e-mail)

# Exhibit 1

### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE,	)	
Plaintiffs,	)	C.A. No. 17-1407-GMS C.A. No. 17-1471-GMS
<b>v.</b> ·	j j	
AMGEN INC.,	)	
Defendant.	)	
	)	

### PLAINTIFFS' OBJECTIONS AND RESPONSES TO AMGEN INC.'S SECOND SET OF REQUESTS FOR THE PRODUCTION OF DOCUMENTS AND THINGS (NOS. 36-76)

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and D. Del. LR 26.1 and 26.2, Plaintiffs Genentech, Inc. and City of Hope (collectively, "Plaintiffs"), by undersigned counsel, hereby object and respond as follows to Defendant's Second Set of Requests for Production.

#### **GENERAL OBJECTIONS & OBJECTIONS TO DEFINITIONS**

Pursuant to D. Del. LR 26.1(b), Plaintiffs provide the following General Objections and Objections to Definitions. These objections form a part of, and are hereby incorporated into, the response to each and every request set forth below. Nothing in those responses, including any failure to recite a specific objection in response to a particular request, should be construed as a waiver of any of these General Objections and Objections to Definitions.

1. <u>Conflicts with Rules</u>. Plaintiffs object to each request, definition, and instruction generally to the extent that they purport to impose obligations or responsibilities different from or in excess of those imposed by the Federal Rules of Civil Procedure and the Local Rules of the

United States District Court for the District of Delaware. Plaintiffs will interpret and respond to the Requests in good faith and in accordance with the Rules.

2. Privileged Information. Plaintiffs object to any part of the Requests calling for the production of information or documents that are privileged or otherwise protected from discovery pursuant to the attorney-client privilege, the accountant-client privilege, the commoninterest privilege, the work product doctrine, or any other applicable privilege, protection, or immunity. Plaintiffs do not agree to produce such information or documents protected from discovery and will withhold or redact information or documents on that basis. If protected information or documents are inadvertently produced in response to the Requests, the production of such information or documents shall not constitute a waiver of Plaintiffs' rights to assert the applicability of any privilege, protection, or immunity to the information or documents, to seek the return of such material, or to object to the use of such material at any stage of the action or in any other action or proceeding.

Plaintiffs will comply with the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the District of Delaware in identifying privileged material, but Plaintiffs specifically object to identifying documents on a document privilege log that were generated subsequent to October 6, 2017 (the filing of *Genentech, Inc. and City of Hope v. Amgen Inc.*, No. 1:17-cv-01407-GMS (D. Del.)) or which reflect communications between Plaintiffs and their trial counsel (Williams & Connolly, Durie Tangri, or McCarter & English) given the irrelevance of such documents and the burden of preparing such a privilege log.

3. <u>Confidential Information Generally</u>. Plaintiffs object to the Requests to the extent that they call for production of trade secret, proprietary, personal, commercially sensitive, third-party confidential, or other confidential information. Plaintiffs will only produce confidential

information, including trade secret, proprietary, personal, commercially sensitive, third-party confidential, or other confidential information, that is responsive, relevant, and not otherwise protected, pursuant to the governing Protective Order and/or D. Del. LR 26.2. Plaintiffs may withhold documents on this basis (as described, for example, in General Objection No. 6), and Plaintiffs may redact from documents that they have otherwise agreed to produce information concerning research or development efforts concerning any molecules other than anti-VEGF antibodies.

- 4. <u>HIPAA Information</u>. Plaintiffs object to the Requests to the extent that they call for production of individually identifiable health information, including without limitation information that would identify patients and persons associated with reporting adverse events involving human drugs and research subjects. *See* 21 C.F.R. §§ 20.63, 314.430. Plaintiffs are withholding such documents or information on this basis and will redact such information from any documents that they produce in this action.
- 5. Personal Information Implicating Foreign Privacy/Data Protection Laws.

  Plaintiffs may, in response to certain of Amgen's requests, produce documents from custodians or non-custodial sources located outside the United States. Foreign privacy laws, over which Plaintiffs have no control, may have a substantial impact on the nature and extent of documents that Plaintiffs can produce from such sources. Plaintiffs object to the Requests to the extent that they call for production of information from any jurisdiction outside that United States that (i) pertains to a specific individual that can be linked to that individual; or (ii) is reasonably believed by Plaintiffs to contain information about or pertaining to a specific individual that can be linked to that individual and that reveals race, ethnic origin, sexual orientation, political opinions, religious or philosophical beliefs, trade union or political party membership or that concerns an

individual's health. Plaintiffs are withholding such documents or information on this basis and will redact such information from any documents that they produce in this action.

- 6. <u>Clinical Development Information</u>. Plaintiffs object to the Requests to the extent that they call for production of information concerning the development of bevacizumab for any indication not already approved by FDA. Such information is extremely commercially sensitive while having essentially no probative value given the parties' claims and defenses. Accordingly, discovery of such information is not proportional to the needs of this case, and Plaintiffs are withholding such documents or information on this basis and will redact such information from any documents that they produce in this action.
- 7. <u>Manufacturing Information</u>. Plaintiffs object to the Requests to the extent that they call for production of information concerning Genentech's methods for manufacturing bevacizumab. Such information is extremely commercially sensitive. Accordingly, discovery of such information may not be proportional to the needs of this case, and Plaintiffs are withholding such documents or information on this basis and will redact such information from any documents that they produce in this action unless otherwise stated.
- 8. <u>Burden and Custodial Scope.</u> Plaintiffs object to each request, definition, and instruction to the extent that it seeks "any" or "all" documents responsive to the request. Such demands are unduly burdensome and overly broad, and they seek documents that are not relevant to the claim or defense of any party nor proportional to the needs of the case (in accordance with Fed. R. Civ. P. 26(b)(1)). Plaintiffs' search for responsive documents and information will be limited to the non-custodial sources and custodians identified by Plaintiffs (for example, as defined below), agreed to by the parties, or ordered by the Court. Absent such agreement or order, Plaintiffs will not search for or produce documents from any other source or location.

Similarly, Plaintiffs object to each request, definition, and instruction as overly broad and unduly burdensome to the extent that it purports to require Plaintiffs to search for and produce electronic documents without reasonable limitations upon the scope of information to be searched or the content of the material to be searched for. Plaintiffs will only produce electronic documents as specifically indicated in their responses and/or in accordance with the electronically stored information ("ESI") protocol that the parties are negotiating to govern this action. To the extent that Amgen's requests conflict with the ESI protocol, Plaintiffs will comply with the ESI protocol. Plaintiffs further object to each definition, instruction, and request to the extent that it seeks documents that are unreasonably cumulative or duplicative, that are publicly available, that are already in the possession, custody, or control of Amgen or Amgen's counsel, that are of no greater burden for Amgen to obtain than Plaintiffs, or that are obtainable from some other source that is more convenient, less burdensome, or less expensive, that are otherwise more appropriately directed to another party, and/or to the extent that compliance would be unduly burdensome, expensive, or oppressive. Unless otherwise indicated specifically below, Plaintiffs will not produce such documents.

9. <u>Subjective Relevance Determinations</u>. Plaintiffs object to each request for documents incorporating or calling for a subjective judgment that a document "concerns" a particular issue, "supports" a particular issue, or "refutes" a particular issue. By their subjective nature, such requests are vague and ambiguous. Such requests also intrude upon the attorneywork product protection by seeking an identification of the documents that counsel considers relevant to a particular issue. To the extent that such requests seek "all" documents, they also are overly broad and unduly burdensome because they fail to account for proportionality.

- 10. <u>Legal Determinations</u>. Plaintiffs object to each request for documents incorporating or calling for a legal conclusion. By incorporating the need to make a legal conclusion, such requests are vague and ambiguous. Such requests also intrude upon the attorney-work product protection by seeking an identification of the documents that counsel believes satisfy the legal contention. To the extent that such requests seek "all" documents, they also are overly broad and unduly burdensome because they fail to account for proportionality.
- 11. <u>No Admission</u>. In furnishing these objections and responses to the requests and in producing documents in response to the requests, Plaintiffs do not admit or concede the relevance, materiality, authenticity, or admissibility in evidence of any such request or document. All objections to the use, at trial or otherwise, of any document produced or information provided in response to the requests and to any further production are hereby expressly reserved.
- 12. <u>No Representation Concerning Existence of Documents</u>. Plaintiffs' statements that they will produce documents in response to a particular request do not mean that they have any such documents, and their response should not be construed in such a manner.
- Timing of Requests and Productions. Plaintiffs object to each discovery request, definition, or instruction to the extent that it prematurely seeks production of information prior to the deadlines provided for such information in any Scheduling Order issued by the Court. Plaintiffs object pursuant to Rule 34(b)(2)(B) to the time specified in Amgen's Requests for Production on the basis that it is not practical, particularly with respect to Amgen's requests that seek information that has not yet been generated. Plaintiffs will make a rolling production of documents in response to Amgen's Requests for Production, with a first production tentatively scheduled for the end of April, 2018. Plaintiffs will complete their production of documents in response to these requests by a date that is reasonable in view of the case's schedule and the

scope and nature of the materials requested by Amgen; Plaintiffs will substantially complete their production of documents by the date set in the Court's scheduling order, and will complete their production no later than September 30, 2019.

- 14. <u>Discovery Related to Claims No Longer Being Asserted</u>. Plaintiffs object to each discovery request, definition, or instruction to the extent that it imposes on Plaintiffs an obligation to provide discovery regarding any patent that, pursuant to the Court's scheduling orders, is no longer being asserted against Amgen.
- 15. <u>Discovery Related to Damages</u>. Plaintiffs object to each discovery request, definition, or instruction to the extent that it seeks information relevant only to Plaintiffs' claim for damages. Such discovery is not reasonably proportional at this time in view of the Court's stated interest in an early resolution of Amgen's contention that Plaintiffs are not entitled to damages. Plaintiffs will supplement further their responses to the Requests when the record concerning the issue of Amgen's contention that Plaintiffs are not entitled to damages has been developed further.
- 16. <u>Discovery Related to City of Hope.</u> City of Hope objects to each discovery request, definition, or instruction to the extent that it obligates City of Hope to search for, or produce, documents in addition to the documents previously produced by Plaintiffs in one or more litigations relating to U.S. Patent No. 6,331,415 and/or U.S. Patent No. 7,923,221. City of Hope will search for and produce additional documents in response to the requests below only upon a showing of good cause, consistent with its proposal in Section B.5 of the Document Production Protocol, or after entry of a Court order declining to adopt City of Hope's proposal.
- 17. Plaintiffs object to Amgen's definition of "Plaintiffs" as overly broad. Plaintiffs interpret those terms to encompass Genentech, Inc. and City of Hope.

18. Plaintiffs expressly reserve the right to supplement these General Objections.

#### **DEFINITIONS**

- 1. As used herein, "BLA Modules" refers to the following sections (excluding attachments) of BLA No. 125085, well as amendments or supplements thereto, which pre-date October 6, 2017:
  - a. Module 1
  - b. Module 2
  - c. Module 3
  - d. Module 4

The term "BLA Modules" specifically *excludes* Module 5 because the burden of reviewing it for information that may be protected by HIPAA and redacting such information (see General Objection No. 4) has not been shown to be reasonably proportional to the needs of this case, particularly in view of the summary clinical information available in the Avastin prescribing information and Module 2.

The term "BLA Modules" further *includes* a copy of each approved version of the Prescribing Information for Avastin.

- 2. As used herein, "Patent Family Documents" refers to:
  - a. A copy of each Patent-in-Suit;
  - b. A copy of the application to which each Patent-in-Suit claims priority;
  - c. A copy of the certified file history of each Patent-in-Suit;
  - d. A copy of any re-examination file history for each Patent-in-Suit;
  - e. Assignment records for each Patent-in-Suit;
- 3. As used herein, "Patent Research Documents" refers to:

- a. for Patents-in-Suit assigned to Genentech, non-privileged documents located after a reasonable search of Genentech's database of lab notebooks for notebooks reflecting research resulting in such patents;
- b. for Patents-in-Suit assigned to Genentech, non-privileged documents located after a reasonable search of Genentech's database of research reports for reports reflecting research resulting in such patents;
- c. for Patents-in-Suit assigned to Hoffmann-La Roche Inc., non-privileged documents located after a reasonable search of Roche's database of lab notebooks for notebooks reflecting research resulting in such patents;
- d. for Patents-in-Suit assigned to Hoffmann-La Roche Inc., non-privileged documents located after a reasonable search of Roche's database of research reports for reports reflecting research resulting in such patents;
- e. non-privileged documents located after a reasonable search of files in the custody of the Named Inventors reflecting research resulting in such patents;

"Patent Research Documents" also includes public presentations or publications by Plaintiffs regarding the Patents-In-Suit located after a reasonable search of Genentech's "Bluesheets" publications archive.

- 4. As used herein, "Avastin® Sales Data" refers to documents sufficient to show revenue from U.S. sales of Avastin generated by the Genentech finance department for the time period beginning January 1, 2017 and updated periodically.
- 5. As used herein, "Licensing Agreements" refers to non-privileged executed licenses, covenants not-to-sue, and settlement agreements related to the Patents-In-Suit, located

after a reasonable search of the files of Plaintiffs' legal departments, and subject to the opportunity to object and/or approval of Plaintiffs' contractual partners.

- 6. As used herein, "Prior Litigation Documents" refers to: (i) non-privileged documents produced by one or more of Plaintiffs in any of the following cases, located after a reasonable search of the files of Plaintiffs' legal departments and/or Plaintiffs' outside counsel in the case; (ii) pleadings filed and discovery responses served by one or more of Plaintiffs in any of the following cases, located after a reasonable search of the files of Plaintiffs' legal departments and/or Plaintiffs' outside counsel in the case, except to the extent such materials contain a third party's confidential information; (iii) transcripts of depositions taken in any of the following cases of witnesses defended by one or more of Plaintiffs' counsel, located after a reasonable search of the files Plaintiffs' legal departments and/or Plaintiffs' outside counsel in the case, except to the extent such pleadings contain a third party's confidential information; and (iv) expert reports served by one or more of Plaintiffs in any of the following cases, located after a reasonable search of the files of Plaintiffs' legal departments and/or Plaintiffs' outside counsel in the case, except to the extent such materials contain a third party's confidential information.

  The cases referred to above consist of:
  - a. Samsung Bioepis Co., Ltd. v. Genentech, Inc., IPR2017-02139 (PTAB)
  - b. Samsung Bioepis Co., Ltd. v. Genentech, Inc., IPR2017-02140 (PTAB)
  - c. Boehringer Ingelheim Pharmaceuticals, Inc. et al v. Genentech, Inc., IPR2017-02031 (PTAB)
  - d. Boehringer Ingelheim Pharmaceuticals, Inc. et al v. Genentech, Inc., IPR2017-02032 (PTAB)
  - e. Pfizer, Inc. v. Genentech, Inc., IPR2017-01489 (PTAB)

- f. Pfizer, Inc. v. Genentech, Inc., IPR2017-01488 (PTAB)
- g. Celltrion, Inc. et al v. Genentech, Inc., IPR2017-01373 (PTAB)
- h. Celltrion, Inc. et al v. Genentech, Inc., IPR2017-01374 (PTAB)
- i. Mylan Pharmaceuticals Inc. v. Genentech, Inc., IPR2016-01693 (PTAB)
- j. Mylan Pharmaceuticals Inc. v. Genentech, Inc., IPR2016-01694 (PTAB)
- k. Merck Sharp & Dohme Corp. v. Genentech, Inc., IPR2017-00047 (PTAB)
- Merck Sharp & Dohme Corp. v. Genentech, Inc., IPR2016-01373 (PTAB)
- m. Mylan Pharmaceuticals Inc. v. Genentech, Inc., IPR2016-00710 (PTAB)
- n. Genzyme Corporation v. GENENTECH, INC., IPR2016-00460 (PTAB)
- o. GENZYME CORPORATION v. Genentech Inc., IPR2016-00383 (PTAB)
- p. Sanofi-Aventis U.S. LLC v. Genentech, Inc., IPR2015-01624 (PTAB)
- q. Merck Sharp & Dohme Corp. v. Genentech, Inc. et al, 2-16-cv-04992 (C.D. Cal.)
- r. Genzyme Corporation v. Genentech, Inc. et al., 2-15-cy-09991 (C.D. Cal.)
- s. Sanofi-Aventis US LLC et al v. Genentech, Inc. et al, 2-15-cv-05685 (C.D. Cal.)
- t. Eli Lilly and Company et al v. Genentech, Inc. et al, 2-13-cv-07248 (C.D. Cal.)
- u. Bristol-Myers Squibb Company v. Genentech, Inc. et al, 2-13-cv-05400 (C.D. Cal.)
- v. Bristol-Myers Squibb Company v. Genentech, Inc. et al, 3-13-cv-02045 (N.D. Cal.)

- w. Eli Lilly and Company et al v. Genentech, Inc. et al, 4-13-cv-00919 (N.D. Cal.)
- x. Human Genome Sciences Inc. v. Genentech Inc. et al, 2-11-cv-06594 (C.D. Cal)
- y. Genentech, Inc. et al v. Glaxo Group Limited et al, 2-11-cv-03065 (C.D. Cal.)
- z. Human Genome Sciences Inc. v. Genentech Inc. et al, 1-11-cv-00328 (D. Del.)
- aa. Human Genome Sciences Inc. v. Genentech Inc. et al, 2-11-cv-06519 (C.D. Cal.)
- bb. Glaxo Group Limited et al v. Genentech, Inc. et al, 2-10-cv-02764 (C.D. Cal.)
- cc. Glaxo Group Limited et al v. Genentech, Inc. et al, 3-10-cv-00675 (N.D. Cal.)
- dd. Glaxo Group Limited et al v. Genentech, Inc. et al, 0-09-cv-61608 (S.D. Fla.)
- ee. Centocor Inc v. Genentech Inc et al, 2-08-cv-03573 (C.D. Cal.)
- ff. MedImmune Inc v. Genentech Inc, et al, 2-03-cv-02567 (C.D. Cal.)
- gg. Boehringer Ingelheim Pharmaceuticals, Inc. et al v. Genentech, Inc., IPR2017-02029 (PTAB)
- hh. Hospira, Inc. v. Genentech, Inc., IPR2016-01771 (PTAB)
- ii. Hospira, Inc. et al v. Genentech, Inc., IPR2016-01837 (PTAB)
- ii. Pfizer, Inc. v. Genentech, Inc., IPR2018-00373 (PTAB)
- kk. Genentech, Inc. v. Celltech Therapeutics, Ltd., 3:1998-cv-03926 (N.D. Cal. Oct. 9, 1998) and/or Interference No. 102,572

Plaintiffs have excluded from the list of cases co-pending BPCIA litigation involving the products Herceptin and Rituxan because those cases are ongoing and involve the

assertion of a substantial number of patents not asserted in these actions, making the production of materials from such cases burdensome and not reasonably proportional to the needs of this case.

- 7. As used herein, "Scientific References" refers to: (i) U.S. Patent Documents cited on the face of a Patent-in-Suit located in the certified file history of the Patent-in-Suit; (ii)

  Foreign Patent Documents cited on the face of a Patent-in-Suit located in the certified file history of the Patent-in-Suit; (iii) Other Publications cited on the face of a Patent-in-Suit located in the certified file history of the Patent-in-Suit; and (iv) references alleged by a biosimilar applicant other than Amgen to constitute prior art to a Patent-in-Suit located after a reasonable search of the files of Plaintiffs' legal departments and/or Plaintiffs' outside counsel for such biosimilar patent litigation.
- 8. As used herein, "Corporate Reports" refers to: (i) a copy of any Form 10-K filed by Genentech for any year from 2004 to the present; and (ii) a copy of any Annual Report distributed by F. Hoffmann-La Roche Ltd for any year from 2004 to the present.
- 9. As used herein, "Marketing Documents" refers to a copy of a representative set of approved marketing publications for Avastin<sup>®</sup> located after a reasonable search of Genentech's archive of approved marketing materials.
- 10. As used herein, "Biosimilar Communications" refers to: (i) non-privileged communications between Plaintiffs and the recipients of subpoenas in the case, located after a reasonable search of the files of Plaintiffs' legal departments and/or Plaintiffs' outside counsel in the case; (ii) non-privileged communications made by F. Hoffmann-La Roche Ltd to investors or potential investors for any year from 2004 to the present concerning biosimilar bevacizumab,

located after a reasonable search of F. Hoffmann-La Roche Ltd's repository of investor communications.

- 11. As used herein, "Adverse Event Reports" refers to adverse event reporting forms filed by Genentech with the Food & Drug Administration prior to the approval of Avastin® that relate to grade III hypertension or gastric perforation following the use of Avastin®, located after a reasonable search of the files of Genentech's regulatory affairs department.
- 12. As used herein, "Inventor Resumes" refers to a copy of the resume and/or curriculum vitae of each of the named inventors of the Patents-in-Suit located after contacting any of the named inventors who are currently employed by a Plaintiff or an affiliate for a copy of an existing resume/curriculum vitae.
- 13. As used herein, "Third Party Documents" refers to documents and things obtained through third party discovery in this litigation.

#### SPECIFIC OBJECTIONS AND RESPONSES

#### **REQUEST FOR PRODUCTION NO. 36:**

The complete prosecution file for each Patent-in-Suit, including any non-privileged drafts or marked-up copies of applications to the Patents-in-Suit or responses to office actions.

#### **RESPONSE TO REQUEST NO. 36:**

Plaintiffs incorporate their General Objections as though fully set forth herein. Plaintiffs object to this request on the grounds that it is unduly burdensome and overly broad, particularly in view of how this request encompasses documents and things that are either irrelevant to any party's claim or defense or not proportional to the needs of the case (in accordance with Fed. R. Civ. P. 26(b)(1)). In particular, Amgen has not articulated a reason why production of "[t]he complete prosecution file for each Patent-in-Suit" is proportionate given that Plaintiffs have

Plaintiffs incorporate their General Objections as though fully set forth herein. Plaintiffs object to this request on the grounds that it is unduly burdensome and overly broad, particularly in view of how this request encompasses documents and things that are either irrelevant to any party's claim or defense or not proportional to the needs of the case (in accordance with Fed. R. Civ. P. 26(b)(1)). As drafted, this request contains no temporal limit, and could be read to encompass documents regarding Plaintiffs' intellectual property licensing during periods that are irrelevant to the claims and defenses of the parties to these actions. Plaintiffs also object to this request to the extent it seeks documents and things protected by the attorney-client privilege, attorney work product doctrine, the common interest privilege and/or any other applicable privilege, see General Objection No. 2.

Subject to and without waiving the foregoing specific and General Objections, and subject to the opportunity to object and/or the approval of Plaintiffs' licensing partners, Plaintiffs will produce the Licensing Agreements and the Corporate Reports.

#### **REQUEST FOR PRODUCTION NO. 63:**

All documents and communications that discuss, describe, or otherwise relate to the grant, receipt, exchange, execution or existence of any license, non-enforcement, covenant, release, immunity from suit, indemnity or other right, title to or interest in any of the Patents-in-Suit.

#### **RESPONSE TO REQUEST NO. 63:**

Plaintiffs incorporate their General Objections as though fully set forth herein. Plaintiffs object to this request on the grounds that it is unduly burdensome and overly broad, particularly in view of the fact that Plaintiffs have already agreed to produce the Licensing Agreements.

Plaintiffs object to this request to the extent it encompasses documents and things that are either

irrelevant to any party's claim or defense or not proportional to the needs of the case (in accordance with Fed. R. Civ. P. 26(b)(1)). For example, Defendant has not identified the proportionality justification for obtaining "all" documents that "relate to" license agreements and covenants where the Patents-In-Suit concern other claims that will not be asserted in the present litigation, or wholly unrelated products or technology. Plaintiffs further object to this request to the extent it seeks documents and things that are equally accessible to Defendant, such as license agreements to which Amgen itself is a party. Plaintiffs also object to this request to the extent it seeks documents that contain confidential or proprietary information, particularly for non-Avastin® drug products, but that are irrelevant or not proportional to the needs of this case, see General Objection No. 3. Plaintiffs also object to this request to the extent it seeks documents and things protected by the attorney-client privilege, attorney work product doctrine, the common interest privilege and/or any other applicable privilege, see General Objection No. 2. Plaintiffs further object to this request because it calls for a subjective relevance determination, see General Objection No. 9.

Subject to and without waiving the foregoing specific and General Objections, and subject to the opportunity to object and/or the approval of Plaintiffs' licensing partners, Plaintiffs will produce the Licensing Agreements, the Prior Litigation Documents, the Biosimilar Communications, and the Patent Family Documents.

#### **REQUEST FOR PRODUCTION NO. 64:**

All documents and communications that discuss, describe, or otherwise relate to any estimate, approximation, or determination of a royalty rate or license fee, or any other measure of the value of any of the Patents-in-Suit, Related Patents and/or Related Applications.

#### **RESPONSE TO REQUEST NO. 64:**

#### Respectfully Submitted,

DATED: May 14, 2018

#### MCCARTER & ENGLISH, LLP

#### /s/ Daniel M. Silver

Michael P. Kelly (# 2295) Daniel M. Silver (# 4758) Renaissance Centre 405 N. King Street, 8th Floor Wilmington, Delaware 19801

Tel.: (302) 984-6300 Fax: (302) 984-6399 mkelly@mccarter.com dsilver@mccarter.com

Attorneys for Plaintiffs Genentech, Inc. and City of Hope

#### OF COUNSEL:

Paul B. Gaffney
David I. Berl
Thomas S. Fletcher
Teagan J. Gregory
Jonathan S. Sidhu
Williams & Connolly LLP
725 Twelfth St. NW
Washington, DC 20005
(202) 434-5000

Attorneys for Plaintiff Genentech, Inc.

# Exhibit 2

1 10:35:22 10:35:27 2 10:35:28 10:35:30 10:35:32 6 10:35:35 10:35:38 7 10:35:40 8 10:35:43 10:35:45 10 10:35:48 11 12 10:35:50 13 10:35:53 10:35:56 14 10:35:59 15 10:36:00 16 17 10:36:03 10:36:07 18 10:36:13 19 20 10:36:16 10:36:19 21 22 10:36:24 23 10:36:27 24 10:36:31 10:36:34 25

is on the party seeking protection to demonstrate why protection is needed.

MR. SILVER: I am not sure I agree with Mr.

Higgins that there is any burden shifting. Under the

protective order, the party that designates the materials as

highly confidential has to do so in good faith.

There may be a question as to who makes the motion in the first instance. Whether it is before Your Honor or another Judge, it is the party that says we require this higher level of protection, that is the one that is going to have to carry the burden at that point in time.

Again, Your Honor, I don't want to take up too much of the Court's time with this issue. The sooner we can get the documents to Amgen the better. It seems to me it makes sense to get the documents in their hand --

THE COURT: Do you disagree with Mr. Silver's analysis, that it doesn't shift the burden?

MR. HIGGINS: I think it does, in the sense that, if they designate them as highly confidential now, Amgen is going to be filing a motion for perhaps de-designation, lowering it to confidential, and the burden would then be on them to demonstrate why highly confidential is appropriate. If they are in the first instance permitted to label these as highly confidential and that's been established by the Court's entering a protective order, then

10:36:37	1
10:36:40	2
10:36:42	3
10:36:45	4
10:36:50	5
10:36:53	6
10:36:53	7
10:36:56	8
10:36:58	9
10:37:01	10
10:37:02	11
10:37:05	12
10:37:06	13
10:37:08	14
10:37:10	15
10:37:12	16
10:37:16	17
10:37:17	18
10:37:19	19
10:37:23	20
10:37:26	21
10:37:29	22
10:37:34	23
10:37:37	24
10:37:37	25

it is going to be Amgen's obligation to show good cause later why that should be undone, effectively.

I still haven't heard a response to the redaction of identities issue. I don't know why any of these third parties would care if we can't even tell who they are.

MR. SILVER: One, Your Honor, that has never been proposed to us and we haven't had a chance to raise it with third parties. That may alleviate some of the concern.

THE COURT: Whether or not you have had a chance to speak with third parties, redaction would seem to cure the problem.

MR. SILVER: It may, Your Honor, if they represent on the record today that they are willing to accept all of the agreements in redacted form so that it is not clear who the counterparties are.

THE COURT: Mr. Higgins?

MR. HIGGINS: Assuming it is just the identities and not substantive information, I think that would be fine.

MR. SILVER: I was handed a note. Any identifying information, so like the names, that sort of thing. They can see, if it is the payment information they are after, that would be unredacted. But the personal identifying information...

THE COURT: Identifying information.

10:37:38	1	Do you agree?
10:37:39	2	MR. HIGGINS: Yes, correct.
10:37:41	3	THE COURT: That's resolved.
10:37:43	4	What about the seal? Should we keep the
10:37:46	5	place I don't like a sealed courtroom, let me just tell
10:37:50	6	you.
10:37:50	7	MR. GREGORY: Your Honor, plaintiffs do not have
10:37:52	8	an opinion one way or the other. I do think Amgen is
10:37:56	9	probably going to disagree with this.
10:37:58	10	THE COURT: I am talking about moving on to the
10:38:00	11	next issue.
10:38:01	12	MR. GREGORY: I understand that, Your Honor.
10:38:02	13	Plaintiffs don't have a view as to whether this third issue
10:38:05	14	needs to be
10:38:06	15	THE COURT: You started out by saying only 4 and
10:38:09	16	5.
10:38:11	17	Open courtroom, counsel, please. We have enough
10:38:17	18	stuff going on in this country in the dark. That is
10:38:20	19	intended to sound just like it does.
10:38:24	20	I am sorry. I am about to retire. I am feeling
10:38:28	21	unbridled.
10:38:31	22	No. 3.
10:38:34	23	MR. GREGORY: Your Honor, hopefully, we can deal
10:38:36	24	with this issue relatively expediently.
10:38:39	25	This issue, as Your Honor may recall, the

# Exhibit 3

### Redacted in its Entirety

# Exhibit 4

## Redacted in its Entirety

# Exhibit 5

### Redacted in its Entirety

# Exhibit 6

### Redacted in its Entirety

### Exhibit 7

### Redacted in its Entirety

### Exhibit 8

#### HANSJORG HAUSER, PH.D. - 01/23/2019

1	IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE
2	FOR THE DISTRICT OF DELAWARE
3	GENENTECH, INC. and :
4	CITY OF HOPE, :
5	Plaintiffs, :
6	vs. :
7	AMGEN, INC., :
8	Defendant. :
	x
9	
10	JANUARY 23, 2019
11	<del></del>
12	**Page 185, Line 13 through Page 189,
13	Line 17 are designated as confidential and will be
14	bound under separate cover**
15	
16	Oral sworn videotaped deposition of
17	HANSJORG HAUSER, Ph.D., taken at the law offices
18	of Williams & Connolly LLP, 725 Twelfth Street,
19	N.W., Washington, DC 20005, before Patricia R.
20	Frank, Registered Merit Reporter, Certified
21	Realtime Reporter, and Notary Public, commencing
22	at 9:11 a.m., on the above date.
23	
24	
25	
2.5	

HANSJORG HAUSER, PH.D. - 01/23/2019

Page 2

1	APPEARANCES:
2	
3	WILLIAMS & CONNOLLY LLP
4	BY: DAVID I. BERL, ESQUIRE BY: THOMAS S. FLETCHER, ESQUIRE BY: LUKE McCLOUD, ESQUIRE
5	725 Twelfth Street, N.W. Washington, D.C. 20005
6	202.434.5491 202.434.5497
7	dberl@wc.com tfletcher@wc.com
8	lmccloud@wc.com  Attorneys for Plaintiff Genentech, Inc.
9	recolling by the reality of the real
10	PROSKAUER ROSE LLP
11	BY: SIEGMUND Y. GUTMAN, ESQUIRE 2049 Century Park East
12	Los Angeles, CA 90067-3206 310.557.2900
13	sgutman@proskauer.com AND
14	PROSKAUER ROSE LLP BY: GOURDIN W. SIRLES, ESQUIRE
15	One International Place Boston, MA 02110-2600
16	617.526.9482 gsirles@proskauer.com
17	Attorneys for Defendent Amgen
18	
19	ALSO PRESENT:
20	EMILY R. WHELAN, ESQUIRE RANA SAWAYA, ESQUIRE
21	EAMONN J. GARDNER, ESQUIRE AMIT THAKORE, ESQUIRE
22	NANCY GETTEL, ESQUIRE (present via livestream)
23	SCOTT FORMAN, VIDEOGRAPHER
24	
25	
1	

Epiq Court Reporting Solutions - Woodland Hills
1-800-826-0277 www.deposition.com

	HANSJO	RG HAUSER, PH.D 01/23/2019	Page 3
1		INDEX	
2	Witness		Page
3	HANSJORG HAUSE	ZR.	
4	By Mr. Gutn	nan 5,	198
5	By Mr. Berl	-	189
6			
7		EXHIBITS	
8	(E	Exhibits attached to transcript in	hard
9	copy format ar	nd/or electronically.)	
10	Marked for I.D.		D =
11	Marked for 1.1	HAUSER EXHIBITS	Page
12	Exhibit 1	Patent Number 8574869,	60
13	EXHIDIC I	AMG01339651-01339745	60
14	Exhibit 2	Declaration of Dr. Hansjorg Hauser in Support of	71
15		Plaintiffs' Opening Claim Construction Brief	
16	Exhibit 3	Article entitled, "Effect of	150
17	HAIIIDIC 3	Copper Sulfate on Performance of Serum-Free CHO Cell Culture	120
18		Process and the Level of Free Thiol in the Recombinant	
19		Antibody Expressed"	
20			
21	MARKED	PORTIONS REQUESTED BY MR. GUTMAN	
22	By Mr. Gutman	Page Line	
23	by Mr. Gueman	52 20	
24		56 14	
25			

Epiq Court Reporting Solutions - Woodland Hills 1-800-826-0277 www.deposition.com

- 1 declarations and in your deposition testimony in
- 2 that case, did you rely on any confidential
- 3 information in offering your opinions about what
- 4 following fermentation means?
- 5 MR. BERL: Objection.
- 6 THE WITNESS: This material was not
- 7 related to the question of following fermentation.
- 8 BY MR. GUTMAN:
- 9 Q. So you did not rely on any confidential
- 10 information in offering your opinions about what
- 11 following fermentation means in the Celltrion case,
- 12 correct?
- MR. BERL: Objection.
- 14 THE WITNESS: Correct.
- 15 BY MR. GUTMAN:
- Q. And the declarations and the deposition
- 17 testimony that you provided in the Celltrion case on
- 18 claim construction of the term "following
- 19 fermentation" did not refer to any confidential
- 20 information, correct?
- MR. BERL: Objection.
- THE WITNESS: I think I said it already.
- 23 It did not -- it does not rely on that confidential
- 24 information.

25

#### HANSJORG HAUSER, PH.D. - 01/23/2019

Page 24

- 1 BY MR. GUTMAN:
- Now, going back to the invalidity issue 2
- 3 that we talked about. Similarly, did the opinions
- that you provided on the invalidity of the '869 4
- patent in the Celltrion case refer or rely on any 5
- confidential information? 6
- 7 MR. BERL: Objection.
- I'm not aware of any 8 THE WITNESS:
- information, confidential information that was 9
- 10 important or that was the basis for the -- for the
- invalidity arguments. 11
- BY MR. GUTMAN: 12
- Do you have any recollection of what 13 0.
- 14 references, if any, you may have considered in
- connection with your invalidity opinions in the 15
- Celltrion case? 16
- It was one of the exhibits of the Reeves 17 Α.
- patent, R-E-E-V-E-S, that was a matter of the patent 18
- 19 history.
- 20 Any other references that you recall? 0.
- There were other references but I do not 21 Α.
- 22 recall them.
- 23 0. How many references were there?
- I do not exactly know. I studied a lot 24 Α.
- 25 but I don't know which were exactly the documents.

## Exhibit 9

**From:** Sirles, Gourdin W.

Sent: Wednesday, January 23, 2019 7:50 PM

To: McCloud, Luke

Cc: 'msharp@ycst.com'; 'jhiggins@ycst.com'; AmgenABP215; Genentech-Bevacizumab;

'Daralyn Durie'; 'abrausa@durietangri.com'; 'Eneda Hoxha'; 'Eric Wiener'; 'Silver, Daniel';

Ovanesian, Michelle M.

Subject: Genentech v. Amgen, C.A. No. 17-1407 & 17-1471-GMS - Hauser Deposition

Categories: You have been BCC'd or have received this message as part of an email group.

Luke,

I write to address two issues regarding today's deposition of Dr. Hauser.

Frist, I write regarding the revelation that Dr. Hauser provided claim construction opinions in the Genentech/Celltrion Rituxan litigation on the same issues on which he has opined in this case, and that Plaintiffs failed to produce those opinions and related documents (such as exhibits and claim construction briefs) before his deposition today.

As you know, Plaintiffs committed to producing redacted versions of documents from the Genentech/Celltrion case before the January 11, 2019 deadline for substantial completion of document productions. And, at the deposition today, Dr. Hauser confirmed that there was no confidential information in his claim construction declaration or invalidity opinions. Plaintiffs' failure to produce these materials in advance of Dr. Hauser's deposition significantly prejudiced Amgen's ability to effectively examine him today.

Plaintiffs must immediately produce the claim construction and invalidity positions that Dr. Hauser referred to at his deposition today, as well as any related documents, such as deposition testimony or claim construction briefing. If Plaintiffs are unable or unwilling to do so, please provide your availability to meet and confer tomorrow so we can bring this issue to the Court's attention immediately.

Amgen reserves all rights with respect to Plaintiffs' failure to produce these materials before Dr. Hauser's deposition, including recalling Dr. Hauser for a subsequent deposition.

Second, Dr. Hauser stated at his deposition today that he relied upon a number of publications to prepare for his deposition, which were not provided or disclosed to Amgen ahead of time. Dr. Hauser agreed on the record to provide a list of such references after his deposition. Please immediately provide that list of references to Amgen.

Regards, Gourdin

Gourdin W. Sirles

Attorney at Law

Proskauer
One International Place
Boston, MA 02110-2600
d 617.526.9482 f 617.526.9899
GSirles@proskauer.com

greenspaces
Please consider the environment before printing this email.

# Exhibit 10

Page 1 \*\*\* C O N F I D E N T I A L \*\*\* 1 IN THE UNITED STATES DISTRICT COURT 2 FOR THE DISTRICT OF NEW JERSEY 3 Civil Action No. 18-cv-00574 (RMB) (KMW) \_\_\_\_\_x 4 GENENTECH, INC., a Delaware 5 corporation; BIOGEN, INC., a Delaware corporation; HOFFMAN-6 LA ROCHE, INC., a New Jersey 7 corporation; and CITY OF HOPE, a California not-for-profit 8 organization, 9 Plaintiffs, 10 -against-11 CELLTRION, INC., a Korean corporation; CELLTRION HEALTHCARE 12 CO., LTD., a Korean corporation; TEVA PHARMACEUTICALS USA, INC., 13 a Delaware corporation; and TEVA PHARMACEUTICALS INTERNATIONAL 14 GmbH, a Swiss corporation, 15 Defendants. 16 1285 Avenue of the Americas 17 New York, New York August 31, 2018 18 8:37 a.m. 19 VIDEOTAPED DEPOSITION of HANSJÖRG 20 HAUSER, taken by the Defendants, held at the 21 aforementioned time and place, before Sherri 22 23 Flagg, a Registered Professional Reporter, Certified LiveNote Reporter, and Notary Public. 24 25

### Redacted in its Entirety

# Exhibit 11

CONFIDENTIAL - ATTORNEYS' EYES ONLY DR. ANNE SKAJA ROBINSON - 09/21/2018

	DR. ANNE BRACK ROBINSON - 09/21/2016
1	UNITED STATES DISTRICT COURT
2	DISTRICT OF NEW JERSEY
3	X
4	GENENTECH, INC., a Delaware Corporation, BIOGEN, INC., a
5	Delaware Corporation, and CITY OF HOPE, a California not-for-profit
6	organization,  Plaintiffs
7	Civ. Action No. 18-0574(RMB)(KMW)
8	v. CELLTRION, INC., a Korean
9	corporation, CELLTRION HEALTHCARE CO., LTD., a Korean corporation,
10	TEVA PHARMACEUTICALS USA, INC., a
11	
12	GmbH, a Swiss corporation., Defendants.
13	X
14	8:37 a.m. September 21, 2018
15	
16	620 Eighth Avenue New York, New York
17	
18	* CONFIDENTIAL - ATTORNEYS' EYES ONLY *
19	
20	VIDEOTAPED DEPOSITION of DR. ANNE SKAJA
21	ROBINSON, an Expert Witness in the above entitled
22	matter, pursuant to Notice, before Stephen J.
23	Moore, a Registered Professional Reporter,
24	Certified Realtime Reporter and Notary Public of
25	the State of New York.

### Redacted in its Entirety

# Exhibit 12

#### Redacted in its Entirety

## Exhibit 13

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 57 of 123 PageID #:

Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/05/18 Page 1 of 26 PageID: 13115 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 1 of 25 PageID: 13079

#### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

GENENTECH, INC., a Delaware corporation, BIOGEN, INC., a Delaware corporation, HOFFMANN-LA ROCHE INC., a New Jersey corporation, and CITY OF HOPE, a California not-for-profit organization,

Plaintiffs,

v.

CELLTRION, INC., a Korean corporation, CELLTRION HEALTHCARE CO., LTD., a Korean corporation, TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICALS INTERNATIONAL GmbH, a Swiss corporation,

Civil Action No. 18-cv-00574 (RMB)(KMW)

STIPULATED DISCOVERY CONFIDENTIALITY ORDER

Defendants.

It appearing that discovery in this action is likely to involve disclosures of confidential information for which special protection may be warranted, and all parties listed in the above caption consenting to the entry of this stipulated Discovery Confidentiality Order, it is ORDERED as follows:

#### I. <u>DESIGNATING MATERIAL AS "CONFIDENTIAL" OR</u> "ATTORNEYS' EYES ONLY"

1. Any party to the above-captioned litigation (the "Litigation") and any third party who is covered by this Order shall have the right to designate as "Confidential"

Case 1:18-cv-00574-RMB-KMW Document 119 Filed 09/05/18 Page 2 of 26 PageID: 13116 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 2 of 25 PageID: 13080

and subject to this Order any information, document, or thing, or portion of any document or thing: (a) that contains trade secrets, competitively sensitive technical, marketing, financial, sales, or other confidential business information; or (b) that contains private or confidential personal information; or (c) that contains information received in confidence from third parties; or (d) which the producing party otherwise believes in good faith to be entitled to protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure and Local Civil Rule 5.3. Any party to this Litigation or any third party covered by this Order who produces or discloses any Confidential material (the "Designating Party"), including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the following or similar legend: "CONFIDENTIAL" or "CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER" (hereinafter "Confidential").

2. Any party to this Litigation and any third party who is covered by this Order shall have the right to designate as "Attorneys' Eyes Only" and subject to this Order any information, document, or thing, or portion of any document or thing that contains highly sensitive business or personal information, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of the Designating Party, or which a Designating Party believes, in good faith, embodies, contains, or reflects "protected health information" under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Any party to this

Case 1:18-cv-00574-RMB-KMW Document 13646 Piled 09/05/18 Page 3 of 26 PageID: 13117 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 3 of 25 PageID: 13081

Litigation or any third party who is covered by this Order who produces or discloses any Attorneys' Eyes Only material, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the following or similar legend: "ATTORNEYS' EYES ONLY" or "ATTORNEYS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER" (hereinafter "Attorneys' Eyes Only"). Confidential material and Attorneys' Eyes Only material shall be collectively referred to herein as "Protected Material."

3. The protections conferred by this Order cover not only Confidential material and Attorneys' Eyes Only material (as designated above) obtained by the parties from one another and from third parties or non-parties, but also (1) any information copied or extracted from Protected Material; (2) all copies, excerpts, summaries, or compilations of Protected Material; and (3) any testimony, conversations, or presentations by parties or their counsel that might reveal Protected Material.

#### II. ACCESS TO AND USE OF PROTECTED MATERIAL

4. All Protected Material shall be used by the party or parties receiving the disclosure (the "Receiving Party") solely for purposes of the prosecution, defense, or attempted settlement of the Litigation. Protected Material shall not be used by the Receiving Party for any business, commercial, competitive, personal or other purpose, and shall not be disclosed by the Receiving Party to anyone other than those set forth

Case 1:18-cv-00574-RMB-KMW Document 119 Filed 09/05/18 Page 4 of 26 PageID: 13118 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 4 of 25 PageID: 13082

in Paragraphs 5 and 6 below, unless and until the restrictions herein are removed either by written agreement of counsel for the parties, or by Order of the Court. It is, however, understood that counsel for a party may give advice and opinions to his or her client solely relating to the above-captioned action based on his or her evaluation of Protected Material, provided that such advice and opinions shall not reveal the content of such Protected Material except by prior written agreement of counsel for the parties, or by Order of the Court.

- 5. Confidential material and the contents of Confidential material may be disclosed only to the following individuals and under the following conditions:
  - a. Outside counsel (herein defined as any attorney at the parties' outside law firms retained in connection with this action) and its employees/staff responsible for supporting or assisting outside counsel in connection with this action;
  - b. Subject to Paragraph 20, outside experts or consultants retained by outside counsel for purposes of this action, provided they have signed a non-disclosure agreement in the form attached hereto as Exhibit A;
  - c. Secretarial, paralegal, clerical, duplicating, and data processing personnel of the foregoing;
  - d. The Court and court personnel;

Case 1:18-cv-00574-RMB-KMW Document 11647 Filed 09/05/18 Page 5 of 26 PageID: 13119 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 5 of 25 PageID: 13083

- e. Any deponent may be shown or examined on any information, document, or thing designated Confidential if it appears that the witness authored or received a copy of it; was involved in the subject matter described therein or is employed by the party who produced the information, document, or thing; or if the Designating Party consents to such disclosure;
- f. Vendors retained by or for the parties to assist in preparing for pretrial discovery, trial, and/or hearings including, but not limited to, court reporters, videographers, litigation support personnel, jury consultants, and individuals who prepare demonstrative and audiovisual aids for use in the courtroom or in depositions or mock jury sessions, as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials;
- g. Mock jurors or focus group members, provided they have signed a non-disclosure agreement in the form attached hereto as Exhibit B; and
- h. Up to 8 officers, directors, and employees (including relevant in-house counsel) of each side (i.e., 8 for Plaintiffs collectively and 8 for Defendants collectively) to whom disclosure is reasonably necessary for this litigation, provided they have signed a non-disclosure agreement in the form attached hereto as Exhibit A.

Case 1:18-cv-00574-RMB-KMW Document 119 Filed 09/05/18 Page 6 of 26 PageID: 13120 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 6 of 25 PageID: 13084

- 6. Unless otherwise ordered by the Court or permitted in writing by the Designating Party, material produced and marked as Attorneys' Eyes Only may be disclosed only to the persons identified in Paragraph 5 (a)-(g) above, and not to any officers, directors, or employees of the Receiving Party or its affiliates. Notwithstanding the foregoing, a Receiving Party may disclose Attorneys' Eyes Only Material to no more than five (5) officers, directors, and employees (including relevant in-house counsel) of each party with, for purposes of this Section 6 only, Plaintiffs counting as three (3) parties (Genentech, Biogen, Hoffmann-La Roche) (for a total of fifteen (15) authorized persons) and Defendants counting as two (2) parties (Celltrion, Teva) (for a total of ten (10) authorized persons) who are actively advising that party in connection with this litigation (or staff specifically assisting counsel in connection with this litigation, including patent agents or other IP department members) and to whom disclosure is reasonably necessary for this litigation ("In-House Counsel"). Prior to the disclosure of any Attorneys' Eyes Only Material to any designated In-House Counsel, such In-House Counsel shall sign a non-disclosure agreement in the form attached hereto as Exhibit A and shall be identified in writing to the other party at least seven (7) calendar days
  - a. Unless the other party notifies the proposing party of any objection within seven (7) calendar days after notification, the In-House Counsel shall thereafter be allowed to have access to Attorneys' Eyes Only Material

before any Attorneys' Eyes Only Material is disclosed to such person.

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 63 of 123 PageID #: Case 1:18-cv-00574-RMB-KMW Document 12/947 Filed 09/05/18 Page 7 of 26 PageID: 13121

1

Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 7 of 25 PageID: 13085

pursuant to the terms and conditions of this Discovery Confidentiality Order on the further condition that they do not engage formally or informally in the following activities for the pendency of this action and for one year subsequent to this action: (1) any patent prosecution¹ relating to Rituxan® (rituximab) or its biosimilars (including Truxima/CT-P10) and/or any of the technologies involved in the manufacturing or processing of Rituxan® (rituximab) or its biosimilars (including Truxima/CT-P10) and (2) any FDA-related counseling, FDA-related litigation, or other FDA-related work related to the approval of the Celltrion BLA or BLA fillings by Plaintiffs, including but not limited to the preparation or submission of any FDA correspondence (e.g., citizen petitions), or any similar correspondence in any foreign country, regarding approval requirements for rituximab products.

b. For the avoidance of doubt, nothing in the preceding paragraphs shall prohibit any party's In-House Counsel who receive access to Attorneys'

Eyes Only Material from engaging in FDA-related activities in support of

<sup>&</sup>lt;sup>1</sup> For purposes of this Confidentiality Order, "patent prosecution" does not include representing a party in a post-grant proceeding before the United States Patent and Trademark Office so long as such practice does not involve claim amendments. For the avoidance of doubt, the restrictions in this Confidentiality Order on participation in patent prosecution and litigation or in FDA-related matters are specific to individual attorneys, staff, consultants, and experts and shall not apply to individuals, even within the same firm or company, who do not access, receive, or otherwise obtain Protected Material provided under this agreement.

Case 1:18-cv-00574-RMB-KMW Document 119 Filed 09/05/18 Page 8 of 26 PageID: 13122

Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 8 of 25 PageID: 13086

the party's own BLA or aBLA filings. However, nothing in this provision shall be construed as contradicting the prohibition against citizen petitions or other activities in opposition to another party's FDA filings or as allowing the use of Attorneys' Eyes Only Material in connection with any FDA related activities, the parties expressly reiterating here that all Protected Material shall be used by the Receiving Party solely for purposes of the prosecution, defense, or attempted settlement of the Litigation.

- c. In the event of a timely objection, which shall be in good faith and which shall be based solely on the existence of a conflict or prejudice to the objecting party, the proposing party shall refrain from disclosure of Attorneys' Eyes Only Material to the In-House Counsel until the objection has been resolved between the parties or ruled upon by the Court;
- d. The parties shall endeavor in good faith to resolve the dispute without calling upon the intervention of the Court. The burden is on the objecting party to seek the intervention of the Court by appropriate application pursuant to Local Civil Rule 37.1(a)(1) to preclude the proposing party from disclosing Attorneys' Eyes Only Material to the In-House Counsel.

  If no such application is filed within ten (10) business days of the

Case 1:18-cv-00574-RMB-KMW Document 12947 Filed 09/05/18 Page 9 of 26 PageID: 13123

Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 9 of 25 PageID: 13087

objection, the proposing party may disclose Protected Material to the In-House Counsel as if no objection had been raised; and

- e. No party shall use its right to object to an In-House Counsel to interfere with the ability of another party to conduct its case and prepare for trial.
- 7. Protected Material shall be used only by individuals permitted access to it under Paragraphs 5 and 6. Protected Material, copies thereof, and the information contained therein, shall not be disclosed in any manner to any other individual, until and unless (a) outside counsel for the party asserting confidentiality waives the claim of confidentiality; or (b) the Court orders such disclosure.
- 8. With respect to any depositions that involve a disclosure of Protected Material of a party to this action, the Designating Party shall have until thirty (30) calendar days after receipt of the deposition transcript within which to inform all other parties that portions of the transcript are to be designated Confidential or Attorneys' Eyes Only, which period may be extended by agreement of the parties. No such deposition transcript shall be disclosed to any individual other than the individuals described in Paragraph 5(a), (b), (c), (d), (f) and (g) above, the persons allowed under Paragraph 6 above, and the deponent during these thirty (30) days, and no individual attending such a deposition shall disclose the contents of the deposition to any individual other than those described in Paragraph 5(a), (b), (c), (d), (f) and (g) and the persons allowed under Paragraph 6 above during said thirty (30) days. Upon being

informed that certain portions of a deposition are to be designated as Confidential or Attorneys' Eyes Only, all parties shall immediately cause each copy of the transcript in its custody or control to be appropriately marked and limit disclosure of that transcript in accordance with Paragraphs 5 and 6.

#### III. DESIGNATING PROTECTED MATERIAL

- 9. Each party or non-party that designates information or items for protection under this Order must take care to limit any such designation to specific material that qualifies under the appropriate standards. If it comes to a Designating Party's attention that information or items that it designated for protection do not qualify for protection, the Designating Party must promptly notify all other parties that it is withdrawing the mistaken designation.
- 10. Except as otherwise provided in this Order or as otherwise agreed by the parties, stipulated or ordered (such as when documents are produced for inspection at a party's or its counsel's facilities), disclosure of discovery material that qualifies for protection under this Order must be clearly designated as Confidential or Attorneys' Eyes Only before or when the material is disclosed or produced. For example, for Protected Material in documentary form (but excluding transcripts of depositions or other pretrial or trial proceedings), the designating party must affix the word "CONFIDENTIAL" or the words "ATTORNEYS' EYES ONLY" to each page that contains material to be protected. To the extent materials have already been produced

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 67 of 123 PageID #: Case 1:18-cv-00574-RMB-KMW Document 1264 Filed 09/05/18 Page 11 of 26 PageID: 13125 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 11 of 25 PageID: 13089

pursuant to an agreement of the parties to keep those materials confidential, but have not been specifically marked in accordance with this Paragraph 10, such agreement will continue in force notwithstanding this Paragraph 10.

11. Copies of documents produced in this matter, whether pursuant to a formal discovery request or otherwise, shall bear a unique identifying number where possible, except such unique identifying number is not required when documents are produced only for inspection.

#### IV. CHALLENGING CONFIDENTIALITY DESIGNATIONS

- 12. If counsel for a Receiving Party upon receiving documents or information designated as Confidential or Attorneys' Eyes Only hereunder objects to such designation of any or all of such items, the following procedure shall apply:
  - a) Counsel for the objecting party shall serve on the Designating Party or third party a written objection to such designation, which shall describe with particularity the documents or information in question and shall state the grounds for objection. Counsel for the Designating Party or third party shall respond in writing to such objection within fourteen calendar (14) days, and shall state with particularity the grounds for asserting that the document or information is Confidential or Attorneys' Eyes Only. If no timely written response is made to the objection, the challenged designation will be deemed to be void. If the Designating Party or third

Case 1:18-cv-00574-RMB-KMW Document 119 Filed 09/05/18 Page 12 of 26 PageID: 13126 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 12 of 25 PageID: 13090

party makes a timely response to such objection asserting the propriety of the designation, counsel shall then confer in good faith in an effort to resolve the dispute.

b) If a dispute as to a Confidential or Attorneys' Eyes Only designation of a document or item of information cannot be resolved by agreement, the challenger of the designation shall present the dispute to the Court initially by telephone or letter, in accordance with Local Civil Rule 37.1(a)(1), before filing a formal motion for an order regarding the challenged designation. The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute.

### V. <u>A NON-PARTY'S PROTECTED MATERIAL SOUGHT TO BE</u> PRODUCED IN THIS MATTER

13. The terms of this Order are applicable to information produced by a non-party in this Litigation and designated as "CONFIDENTIAL" or "ATTORNEYS' EYES ONLY." Such information produced by non-parties in connection with this matter is protected by the remedies and relief provided by this Order. Nothing in these provisions should be construed as prohibiting a non-party from seeking additional protections.

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 69 of 123 PageID #:

Case 1:18-cv-00574-RMB-KMW Document 1164 Filed 09/05/18 Page 13 of 26 PageID: 13127 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 13 of 25 PageID: 13091

#### VI. DISCLOSURE OF PROTECTED MATERIAL TO THE COURT

- 14. All requests to seal documents filed with the Court shall comply with Local Civil Rule 5.3.
- 15. If the need arises during trial or at any Hearing before the Court for any party to disclose Confidential or Attorneys' Eyes Only information, it may do so only after giving notice to the Producing Party and as directed by the Court.

### VII. INADVERTENT DISCLOSURE OF PRIVILEGED OR OTHERWISE PROTECTED MATERIAL

16. To the extent consistent with applicable law, the inadvertent or unintentional disclosure of Protected Material that should have been designated as such, regardless of whether the information, document, or thing was so designated at the time of disclosure, shall not be deemed a waiver in whole or in part of a party's claim of confidentiality, either as to the specific information, document, or thing disclosed or as to any other material or information concerning the same or related subject matter. Such inadvertent or unintentional disclosure may be rectified by notifying in writing counsel for each Receiving Party that the material should have been designated Confidential or Attorneys' Eyes Only within a reasonable time after discovery of the erroneous failure to designate. Such notice shall constitute a designation of the information, document, or thing as Confidential or Attorneys' Eyes Only under this Discovery Confidentiality Order. Upon correction of a designation, the Receiving Party

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 70 of 123 PageID #:

Case 1:18-cv-00574-RMB-KMW Document 119 Filed 09/05/18 Page 14 of 26 PageID: 13128

Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 14 of 25 PageID: 13092

shall take reasonable efforts to ensure that the material is treated in accordance with the provisions of this agreement. No demonstration or proof of error, inadvertence, excusable neglect, or absence of negligence shall be required of the Designating Party in order for such party to avail itself of the provisions of this paragraph.

- 17. The production or disclosure of any information (including documents) in this action that a Producing Party later claims should not have been produced due to a privilege or protection from discovery, including but not limited to any attorney-client privilege or work product protection, shall not be deemed to waive any such privilege or protection. This Order should be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d). The treatment of any such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5) and this agreement, with this agreement governing in the event of any conflict. When a Producing Party requests the return or destruction of such information, which request shall identify the information and the basis for requesting its return, the Receiving Party shall promptly return the information to the Producing Party.
- 18. When a Producing Party or Receiving Party identifies such privileged or protected information, a Receiving Party: 1) shall not use, and shall immediately cease any prior use of, such information; 2) shall take reasonable steps to retrieve the information from others to whom the Receiving Party disclosed the information; 3) shall within five (5) business days of the Producing Party's request return to the Producing Party or destroy the information and destroy all copies thereof; and 4) shall

confirm to the Producing Party the destruction under 3) above of all copies of the information not returned to the Producing Party.

19. No one shall use the fact or circumstances of production of the information in this action to argue that any privilege or protection has been waived. Notwithstanding any provision of Federal Rule of Civil Procedure 26(b)(5), the Receiving Party may not reference or make any use of the contents of the information at issue in connection with such a motion to challenge the designation of any inadvertently produced materials. The Producing Party and the Receiving Party shall meet and confer prior to any such motion to compel. Nothing herein restricts the right of the Receiving Party to challenge the Designating Party's claim of privilege or immunity, if appropriate, within a reasonable time after receiving notice of the inadvertent production.

#### VIII. DISCLOSURE TO CONSULTANTS AND EXPERTS

- 20. Protected Material shall be disclosed to consultants and experts only upon the following terms:
  - a) Consultants and experts who were allowed to review confidential information under 42 U.S.C. § 262(!)(1) can review Protected Material without regard to the remaining provisions of this Paragraph;

Case 1:18-cv-00574-RMB-KMW Document 261982 Filed 09/05/18 Page 16 of 26 PageID: 13130 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 16 of 25 PageID: 13094

- b) Prior to a Receiving Party giving, showing, disclosing, making available, or communicating Protected Material, the consultant or expert shall be identified in writing to the other parties' counsel by name, address, and corporate, business, or other professional affiliation or employment, together with a copy of the expert's current curriculum vitae. If not contained within the curriculum vitae, the disclosing party shall provide a list of the expert's other or former consulting engagements with the parties or their affiliates, and if the consultant or expert has consulted in the pharmaceutical and/or biotechnology industry in the past three (3) years, the disclosing party shall also provide to the other parties' counsel a list of the expert's consulting engagements for the past three (3) years, provided that if the expert or consultant is prevented from disclosing the details of a consulting relationship because of a confidentiality or non-disclosure agreement, the expert or consultant shall be permitted instead to disclose generally the subject matter or industry involved in the consulting relationship;
- c) Unless the other party notifies the proposing party of any objection within seven (7) calendar days after notification, the consultant or expert shall thereafter be allowed to have access to Protected Material pursuant to the terms and conditions of this Discovery Confidentiality Order on the

Case 1:18-cv-00574-RMB-KMW Document 14644 led 09/05/18 Page 17 of 26 PageID: 13131 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 17 of 25 PageID: 13095

- further condition that they do not engage formally or informally in any activities set forth in Section II.6.a, supra.
- d) In the event of a timely objection, which shall be in good faith and which shall be based solely on the existence of a conflict or prejudice to the objecting party, the proposing party shall refrain from disclosure of Protected Material to the consultant or expert until the objection has been resolved between the parties or ruled upon by the Court;
- e) The parties shall endeavor in good faith to resolve the dispute without calling upon the intervention of the Court. The burden is on the objecting party to seek the intervention of the Court by appropriate application pursuant to Local Civil Rule 37.1(a)(1) to preclude the proposing party from disclosing Protected Material to the consultant or expert. If no such application is filed within ten (10) business days of the objection, the proposing party may disclose Protected Material to the consultant or expert as if no objection had been raised; and
- f) No party shall use its right to object to a proposed consultant or expert to interfere with the ability of another party to conduct its case and prepare for trial through the use of consultants and experts.

### IX. MISCELLANEOUS

- 21. If a Receiving Party learns that, by inadvertence or otherwise, it has disclosed Protected Material to any person or in any circumstance not authorized under this agreement or because of a subsequent correction of an inadvertent failure to designate pursuant to this agreement, the Receiving Party must immediately (a) use its best efforts to retrieve all unauthorized copies of the protected material; (b) inform the person or persons to whom unauthorized disclosures were made of all the terms of this agreement; and (c) request that such person or persons execute a non-disclosure agreement in the form attached hereto as Exhibit A. The Receiving Party must also promptly inform the Disclosing Party of the unauthorized disclosure.
- 22. No information that is in the public domain or which is already known by the Receiving Party through proper means or which is or becomes available to a party from a source other than the party asserting confidentiality, rightfully in possession of such information on a non-confidential basis, shall be deemed or considered to be Protected Material under this Discovery Confidentiality Order.
- 23. This Discovery Confidentiality Order shall not deprive any party of its right to object to discovery by any other party or on any otherwise permitted ground. Nor shall this Order be construed to affect in any way the evidentiary admissibility of any document, testimony, or other material designated as Protected Material.

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 75 of 123 PageID #:

Case 1:18-cv-00574-RMB-KMW Document 14644 Filed 09/05/18 Page 19 of 26 PageID: 13133

Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 19 of 25 PageID: 13097

24. This Discovery Confidentiality Order is being entered without prejudice to the right of any party to move the Court for modification or for relief from any of its terms. The parties specifically reserve the right to move the Court to modify this Discovery Confidentiality Order, or to negotiate and enter into a separate agreement, permitting the additional use of Protected Material, including in other legal proceedings not provided for herein.

- 25. This Discovery Confidentiality Order shall survive the termination of this action and shall remain in full force and effect unless modified by an Order of this Court or by the written stipulation of the parties filed with the Court.
- 26. Within sixty (60) calendar days after the termination of this action, including all appeals, each party or other individual subject to the terms of this Order shall assemble and return to the Producing Party, or destroy and certify by email destruction of, all originals of documents and things containing Protected Material and shall destroy, upon the Producing Party's request, all copies of Protected Material that contain and/or constitute attorney work product as well as excerpts, summaries, and digests revealing Protected Material. Notwithstanding this provision, counsel are entitled to retain archival copies of all documents filed with the court, trial, deposition, and hearing transcripts, correspondence, deposition and trial exhibits, expert reports, attorney work product, and consultant and expert work product, even if such materials contain Protected Material, subject to the provisions of this Discovery Confidentiality Order. Protected Material, including all hard and electronic copies, derivations and

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 76 of 123 PageID #:

Case 1:18-cv-00574-RMB-KMW Document 119 Filed 09/05/18 Page 20 of 26 PageID: 13134

Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 20 of 25 PageID: 13098

summaries thereof, may also be retained if it is required to be retained under a Party's

retention policy or if it is subject to a legal duty to preserve existing at the conclusion

of this Proceeding, provided that confidentiality is maintained in accordance with this

Order. Finally, notwithstanding this provision, no party shall be required to return or

destroy any materials designated under this Order that may exist on any disaster

recovery backup system. To the extent a party requests the return of Protected Material

from the Court after the final conclusion of the litigation, including the exhaustion of

all appeals therefrom and all related proceedings, the party shall file a motion seeking

such relief.

Dated: September 4, 2018

/s/Keith J. Miller

Counsel for Plaintiffs

Dated: September 4, 2018

<u> | s|Liza Walsh</u>

Counsel for Defendants

IT IS SO ORDERED.

Dated September 5,0018

The Honorable Karen M. Williams, U.S.M.I.

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 77 of 123 PageID #:

Case 1:18-cv-00574-RMB-KMW Document 1294 Filed 09/05/18 Page 21 of 26 PageID: 13135 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 21 of 25 PageID: 13099

### EXHIBIT A

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

GENENTECH, INC., a Delaware corporation, BIOGEN, INC., a Delaware corporation, HOFFMANN-LA ROCHE INC., a New Jersey corporation, and CITY OF HOPE, a California not-for-profit organization,

Plaintiffs,

v.

CELLTRION, INC., a Korean corporation, CELLTRION
HEALTHCARE CO., LTD., a Korean corporation, TEVA
PHARMACEUTICALS USA, INC., a
Delaware corporation, and TEVA
PHARMACEUTICALS
INTERNATIONAL GmbH, a Swiss corporation,

Defendants.

Civil Action No. 18-cv-00574 (RMB)(KMW)

AGREEMENT TO BE BOUND BY DISCOVERY CONFIDENTIALITY ORDER

I,	, being duly sworn, state that:				
	1.	My address is			
	2.	My present employer is			
and	the add	ress of my present employment is			
		•			

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 78 of 123 PageID #:

Case 1:18-cv-00574-RMB-KMW Document 119 Filed 09/05/18 Page 22 of 26 PageID: 13136 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 22 of 25 PageID: 13100

3. My present occupation or job description is

4. I have carefully read and understood the provisions of the Discovery Confidentiality Order in this case signed by the Court, and I will comply with all provisions of the Discovery Confidentiality Order.

- 5. I will hold in confidence and not disclose to anyone not qualified under the Discovery Confidentiality Order any Protected Material or any words, summaries, abstracts, or indices of Protected Material disclosed to me.
- 6. I will limit use of Protected Material disclosed to me solely for purpose of this action.
- 7. I agree not engage formally or informally in the following activities for the pendency of this action and for one year subsequent to this action: (1) any patent prosecution relating to Rituxan® (rituximab) or its biosimilars (including Truxima/CT-P10) and/or any of the technologies involved in the manufacturing or processing of Rituxan® (rituximab) or its biosimilars (including Truxima/CT-P10) and (2) any FDA-related counseling, FDA-related litigation, or other FDA-related work related to the approval of the Celltrion BLA or BLA filings by Plaintiffs, including but not limited to the preparation or submission of any FDA correspondence (e.g., citizen petitions), or

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 79 of 123 PageID #: Case 1:18-cv-00574-RMB-KMW Document 11948 Filed 09/05/18 Page 23 of 26 PageID: 13137 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 23 of 25 PageID: 13101

any similar correspondence in any foreign country, regarding approval requirements for rituximab products.2

No later than the final conclusion of the case, I will return all Protected 8. Material and summaries, abstracts, and indices thereof which come into my possession, and documents or things which I have prepared relating thereto, to counsel for the party for whom I was employed or retained.

I declare under penalty of perjury	y that the foregoing is true and correct.
Dated:	
	[Name]

<sup>&</sup>lt;sup>2</sup> For the avoidance of doubt, I understand that nothing in this agreement shall prohibit any party's In-House Counsel who receive access to Attorneys' Eyes Only Material from engaging in FDA-related activities in support of the party's own BLA or aBLA filings. However, I also understand that nothing in this agreement shall be construed as contradicting the prohibition against citizen petitions or other activities in opposition to another party's FDA filings or as allowing the use of Attorneys' Eyes Only Material in connection with any FDA related activities, and I understand that all Protected Material shall be used by the Receiving Party solely for purposes of the prosecution, defense, or attempted settlement of the Litigation.

Case 1:18-cv-00574-RMB-KMW Document 119 Filed 09/05/18 Page 24 of 26 PageID: 13138 Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 24 of 25 PageID: 13102

### EXHIBIT B

### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

GENENTECH, INC., a Delaware corporation, BIOGEN, INC., a Delaware corporation, HOFFMANN-LA ROCHE INC., a New Jersey corporation, and CITY OF HOPE, a California not-for-profit organization,

Plaintiffs,

v.

CELLTRION, INC., a Korean corporation, CELLTRION HEALTHCARE CO., LTD., a Korean corporation, TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICALS INTERNATIONAL GmbH, a Swiss corporation,

Defendants.

Civil Action No. 18-cv-00574 (RMB)(KMW)

ACKNOWLEDGEMENT OF CONFIDENTIALITY ORDER

This	agreement is	entered	into	between	***************************************		***************************************		[Counsel	or
Cons	ultant]					[Name	of	Participant],	residing	at
_ <del></del>				Address	of Pa	rticipant]	<b> .</b>			

1. I, Participant, understand that, in connection with the research project in which I am participating today, I may receive information that is confidential, and that

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 81 of 123 PageID #:

Case 1:18-cv-00574-RMB-KMW Document 14644 led 09/05/18 Page 25 of 26 PageID: 13139

Case 1:18-cv-00574-RMB-KMW Document 116-1 Filed 09/04/18 Page 25 of 25 PageID: 13103

I may not share or disclose that information with anyone (including members of my family) outside of this research group.

- 2. I agree not to disclose any information I learn here today to anyone outside of this research group, or to use such information in any way outside of my participation in this research project today.
- 3. I agree that, at the end of the research project today, I will not keep or take with me any documents or other materials shown to me, or any notes or other records I may make about those documents or other materials shown to me today.
- 4. I understand that action may be taken against me for violating the terms of this agreement.

Dated:	
	[Name of Participant]
Dated:	
	[Name of Counsel or Consultant]

Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 82 of 123 PageID #: 26492

Case 1:18-cv-00574-RMB-KMW Document 119 Filed 09/05/18 Page 26 of 26 PageID: 13140

## Redacted in its Entirety

## Redacted in its Entirety

### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

C.A. No. 17-1407-GMS C.A. No. 17-1471-GMS

### PLAINTIFFS' RULE 26 INITIAL DISCLOSURES

Pursuant to Rule 26 of the Federal Rules of Civil Procedure, the Local Rules of the United States District Court for the District of Delaware, and this Court's Policies and Procedures, Genentech, Inc. ("Genentech") and City of Hope (collectively, "Plaintiffs") submit the following Initial Disclosures. The Initial Disclosures made herein are based upon information reasonably available to Plaintiffs at the present stage of this litigation and the issues as currently defined by the pleadings. Plaintiffs reserve the right to supplement, revise, or otherwise amend the information contained herein as discovery continues. By making these disclosures, Plaintiffs do not represent that they are identifying every document, tangible thing, or witness that may be relevant to the issues in these lawsuits, or on which Plaintiffs may rely in support of their claims or defenses. Nor do Plaintiffs waive their rights to object to any requests for discovery on the basis of any privilege, the work-product doctrine, relevance, undue burden, competency, materiality, hearsay, or any other valid basis.

### I. <u>INDIVIDUALS WITH KNOWLEDGE</u>

Based upon information reasonably available to Plaintiffs at the present time, Plaintiffs identify the following as persons likely to have discoverable information that Plaintiffs may use

to support their claims or defenses, unless such use is solely for impeachment. Plaintiffs reserve the right to supplement their disclosures if they identify any further individuals with discoverable information relevant to their claims or defenses. To the extent that Plaintiffs intend to rely on expert witnesses, those individuals will be identified prior to trial.

Further, Plaintiffs do not consent to or authorize any communication with Plaintiffs' current or former employees or consultants. All communications with Plaintiffs' current employees or consultants or former employees should be made through Plaintiffs' outside counsel.

Name	Subject Matter
Paul J. Carter	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	6,054,297 and U.S. Patent No. 6,407,213;
	information relating to the state of the
	relevant art and the validity of U.S. Patent
	No. 6,054,297 and U.S. Patent No. 6,407,213.
Carol D. Basey	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	6,417,335; information relating to the state of
	the relevant art and the validity of U.S. Patent
	No. 6,417,335.
Vishva Dixit	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	6,586,206; information relating to the state of
	the relevant art and the validity of U.S. Patent
M. 4: C14-1-	No. 6,586,206. Information relating to the conception and
Martin Gawlitzek	reduction to practice of the subject matter
Contact through outside counsel for Plaintiffs.	disclosed and claimed in 8,512,983;
	information relating to the state of the
	relevant art and the validity of 8,512,983.
Philip Lester	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
Contact unrough outside counsel for I laments.	disclosed and claimed in U.S. Patent No.
	6,620,918 and U.S. Patent No. 6,870,034;
	information relating to the state of the
	relevant art and the validity of U.S. Patent
	No. 6,620,918 and U.S. Patent No. 6,870,034.
Kathlyn Pham Lazzareschi	Information relating to the conception and

Name	Subject Matter
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	6,870,034; information relating to the state of
	the relevant art and the validity of U.S. Patent
	No. 6,870,034.
Yvonne Man-yee Chen	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	7,060,269, U.S. Patent No. 7,169,901, U.S.
	Patent No. 7,297,334, and U.S. Patent No.
	7,375,193; information relating to the state of
	the relevant art and the validity of U.S. Patent No. 7,060,269, U.S. Patent No. 7,169,901,
	U.S. Patent No. 7,297,334, and U.S. Patent
	No. 7,375,193.
Rhona M. O'Leary	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	7,807,799, U.S. Patent No. 8,044,017 and
	U.S. Patent No. 8,710,196; information
	relating to the state of the relevant art and the
·	validity of U.S. Patent No. 7,807,799, U.S.
	Patent No. 8,044,017 and U.S. Patent No. 8,710,196.
Christian Klinger	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	8,460,895; information relating to the state of
	the relevant art and the validity of U.S. Patent
Cl. '' T. D. 1' (D. '1	No. 8,460,895.
Christina Teresa Petraglia (Bevilacqua)	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	8,512,983; information relating to the state of the relevant art and the validity of U.S. Patent
	No. 8,512,983.
Yung-Hsiang Kao	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	8,574,869; information relating to the state of
	the relevant art and the validity of U.S. Patent
Michael W. Laird	No. 8,574,869.
Contact through outside counsel for Plaintiffs.	Information relating to the conception and
Contact unrough outside counsel for Flamuits.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No. 8,574,869; information relating to the state of
	the relevant art and the validity of U.S. Patent
	No. 8,574,869.
Melody Trexler Schmidt	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter

Name	Subject Matter
Name	disclosed and claimed in U.S. Patent No.
	8,574,869; information relating to the state of
	the relevant art and the validity of U.S. Patent
	No. 8,574,869.
71. 7. 117	The mastice relating to the concention and
Rita L. Wong	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	8,574,869; information relating to the state of
	the relevant art and the validity of U.S. Patent
	No. 8,574,869.
Daniel P. Hewitt	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
·	8,574,869; information relating to the state of
	the relevant art and the validity of U.S. Patent
•	No. 8,574,869.
Veronica Carvalhal	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
Contact anough custom commercial	disclosed and claimed in U.S. Patent No.
	9,441,035; information relating to the state of
	the relevant art and the validity of U.S. Patent
	No. 9,441,035.
Natarajan Vijayasankaran	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
Contact unough outside counsel for Framulis.	disclosed and claimed in U.S. Patent No.
	9,441,035; information relating to the state of
	the relevant art and the validity of U.S. Patent
	No. 9,441,035.
Thomas DiRocco	Information relating to the conception and
	reduction to practice of the subject matter
Contact through outside counsel for Plaintiffs.	disclosed and claimed in U.S. Patent No.
	9,441,035; information relating to the state of
	the relevant art and the validity of U.S. Potent
	the relevant art and the validity of U.S. Patent
	No. 9,441,035.
Nathan McKnight	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	9,441,035; information relating to the state of
	the relevant art and the validity of U.S. Patent
	No. 9,441,035.
Meixia Zhou	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	9,487,809; information relating to the state of
	the relevant art and the validity of U.S. Patent
	No. 9,487,809.
Bradley Richard Snedecor	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	9,487,809; information relating to the state of
	1 2, 101,002, initotitianion to the state of

Name	Subject Matter
	the relevant art and the validity of U.S. Patent
	No. 9,487,809
Amy Shen	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	9,487,809; information relating to the state of
	the relevant art and the validity of U.S. Patent
	No. 9,487,809.
Shmuel Cabilly	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	6,331,415 and U.S. Patent No. 7,923,221;
	information relating to the state of the
	relevant art and the validity of U.S. Patent No. 6,331,415 and U.S. Patent No. 7,923,221.
Herbert L. Heyneker	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	6,331,415 and U.S. Patent No. 7,923,221;
	information relating to the state of the
	relevant art and the validity of U.S. Patent
	No. 6,331,415 and U.S. Patent No. 7,923,221.
William E. Holmes	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	6,331,415 and U.S. Patent No. 7,923,221;
	information relating to the state of the
	relevant art and the validity of U.S. Patent
Arthur D. Riggs	No. 6,331,415 and U.S. Patent No. 7,923,221. Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	6,331,415 and U.S. Patent No. 7,923,221;
	information relating to the state of the
	relevant art and the validity of U.S. Patent
	No. 6,331,415 and U.S. Patent No. 7,923,221.
Ronald B. Wetzel	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	6,331,415 and U.S. Patent No. 7,923,221; information relating to the state of the
	information relating to the state of the
	relevant art and the validity of U.S. Patent No. 6,331,415 and U.S. Patent No. 7,923,221.
L. Jeanne Perry	Information relating to the conception and
Contact through outside counsel for Plaintiffs.	reduction to practice of the subject matter
	disclosed and claimed in U.S. Patent No.
	6,331,415 and U.S. Patent No. 7,923,221;
	information relating to the state of the
	relevant art and the validity of U.S. Patent
	No. 6,331,415 and U.S. Patent No. 7,923,221.

Name	Subject Matter
Tim Schwartz	Information relating to the licensing of U.S.
Contact through outside counsel for Plaintiffs.	Patent No. 7,923,221.
Greg Sund	Information relating to damages.
Contact through outside counsel for Plaintiffs.	
Current and former employees of City of	Information relating to City of Hope's
Hope.	ownership and licensing of certain Patents-in-
Contact through outside counsel for City of	Suit.
Hope.	
Current and former employees of Amgen Inc.,	Information relating to the design,
as well as related entities, affiliates,	development, operation, and manufacture of
predecessors, and successors in interest.	ABP 215/Mvasi; information relating to the
Contact through outside counsel for Defendant.	importation, marketing, and sale of ABP 215/Myasi, including training materials and
Defendant.	sales/detailing aids; Amgen's knowledge and
	awareness of the Patents-in-Suit; Amgen's
	aBLA and related documents and
	correspondence relating to ABP 215/Mvasi,
	including proposed labels for ABP
	215/Myasi; Corporate structure of Amgen and
	its affiliates.

In addition to the above-named individuals, other persons identified in the documents described in Section II below may have discoverable information that Plaintiffs may use to support their claims or defenses. Plaintiffs reserve the right to modify and supplement the foregoing list and to identify and call as witnesses additional persons if, during the course of discovery and investigation relating to this case, Plaintiffs learn that such additional persons have knowledge or information that Plaintiffs may use to support their claims.

Further, Plaintiffs also reserve the right to call as witnesses individuals in addition to those identified herein to the extent such witnesses are required to authenticate an exhibit offered into evidence or to establish chain of custody of an exhibit offered into evidence. Plaintiffs also may rely on expert witnesses, to be disclosed in accordance with Federal Rule of Civil Procedure 26(a)(2), to support their claims or defenses. Plaintiffs specifically reserve the right to call any deponent or declarant in this action as a trial witness to testify regarding matters covered in his/her deposition or declaration and/or to rely on any such testimony in support of their claims

or defenses in this case. Plaintiffs further specifically reserve the right to call any individual(s) identified in Defendant's disclosures.

### II. CATEGORIES OF RELEVANT DOCUMENTS

At present, Plaintiffs believe that the following documents, electronically stored information, and tangible things may be used to support Plaintiffs' claims, unless such use is solely for impeachment. With the exception of item 9 below, this disclosure does not include documents solely within Defendant's possession, custody, or control. This disclosure does not include expert materials that may be or have been developed, which will be disclosed pursuant to Federal Rule of Civil Procedure 26(a)(2). This disclosure does not constitute an admission as to the existence, relevance, or admissibility of the identified materials or a waiver of any attorney-client privilege, work-product protection, or other applicable privilege or immunity.

- 1. The Patents-In-Suit<sup>1</sup> and their prosecution histories.
- 2. Documents related to the ownership of the Patents-In-Suit.
- 3. Documents relating to the validity of the Patents-In-Suit.
- 4. Documents related to the conception and reduction to practice of the inventions claimed in the Patents-In-Suit.
- 5. Documents relating to Plaintiffs' licensing of the Patents-in-Suit.
- 6. Documents relating to the damages to which Plaintiffs are entitled in this lawsuit.
- 7. Documents concerning the development program that led to the invention of bevacizumab, the properties of bevacizumab, and the use of bevacizumab.
- 8. Approved package insert for Avastin<sup>®</sup> in the United States.
- 9. Documents sufficient to show the sales and marketing of Avastin® in the United States.

<sup>&</sup>lt;sup>1</sup> U.S. Patent No. 6,054,297; U.S. Patent No. 6,121,428; U.S. Patent No. 6,242,177; U.S. Patent No. 6,331,415; U.S. Patent No. 6,407,213; U.S. Patent No. 6,417,335; U.S. Patent No. 6,586,206; U.S. Patent No. 6,620,918; U.S. Patent No. 6,870,034; U.S. Patent No. 6,884,879; U.S. Patent No. 7,060,269; U.S. Patent No. 7,169,901; U.S. Patent No. 7,297,334; U.S. Patent No. 7,375,193; U.S. Patent No. 7,622,115; U.S. Patent No. 7,807,799; U.S. Patent No. 7,923,221; U.S. Patent No. 8,044,017; U.S. Patent No. 8,460,895; U.S. Patent No. 8,512,983; U.S. Patent No. 8,574,869; U.S. Patent No. 8,633,302; U.S. Patent No. 8,710,196; U.S. Patent No. 9,441,035; U.S. Patent No. 9,487,809; U.S. Patent No. 9,795,672.

- 10. Documents demonstrating objective indicia of non-obviousness of the inventions claimed in the Patents-In-Suit.
- 11. Documents demonstrating irreparable harm to Plaintiffs from Defendant's launch, or threat to launch, of its bevacizumab biosimilar product, ABP 215 (Mvasi).
- 12. Expert materials, analyses, and documents that may be produced in connection with this litigation.
- 13. Documents relating to Defendant's knowledge and awareness of the Patents-in-Suit.
- 14. Defendant's ABP 215 aBLA.
- 15. Documents relating to the design, development, operation, manufacture, marketing, and sale of ABP 215 (Mvasi), or any other proposed biosimilar copy of Avastin<sup>®</sup> (bevacizumab) designed, developed, manufactured, imported, offered for sale, or sold by Defendant.
- 16. Documents relating to any proposed labels prepared by Defendant and submitted to the FDA, together with related correspondence between Defendant and the FDA concerning such labels.

Plaintiffs will produce or make the documents in categories 1-12 available for inspection after the Court enters a mutually acceptable protective order, subject to any applicable privacy or other restrictions, and at such time specified by the Federal Rules of Civil Procedure, the Local Rules, and/or any applicable scheduling order. Notwithstanding this identification of these categories of documents, Plaintiffs reserve the right to object to any of Defendant's discovery requests on related topics to the extent such requests are overly broad, unduly burdensome, and/or call for documents beyond the scope of Plaintiffs' discovery obligations under the Federal Rules of Civil Procedure or the Local Rules, and/or on any other applicable basis for objection.

Plaintiffs continue to search for additional documents and information that they may use to support their claims, and expressly reserve the right to supplement this disclosure with such additional documents or information.

In addition to the above-described documents, Plaintiffs may also rely upon publicly available documents, documents produced by Defendant, or documents produced by third parties

in this or other litigations. Plaintiffs also expect that experts may identify documents used to support their opinions pertaining to the issues in this case during the course of expert discovery.

### III. CALCULATION OF DAMAGES

Given the procedural posture of this case, the state of discovery, and the need for expert testimony to assess the scope of the injury, Plaintiffs are not yet in a position to compute with precision their damages in this action. For example, Plaintiffs do not yet have necessary information regarding the manufacture, importation, marketing, and sale of ABP 215, as that information is or will be in the possession, custody, or control of Defendants and has not been produced to Plaintiffs. Plaintiffs intend to seek all relief and recover all remedies available under the Patent Act, including a reasonable royalty, lost profits and pre- and post-judgment interest, and will provide an expert report quantifying their damages in accordance with the case schedule. Plaintiffs also claim enhanced damages for willful infringement and their attorneys' fees and costs. Plaintiffs are still investigating whether other damages claims are appropriate.

### IV. INSURANCE

Plaintiffs are not aware of any relevant insurance agreements. To the extent Defendant has any insurance agreement(s) to satisfy all or part of a judgment which may be entered in the action against them or to indemnify or reimburse for payments made to satisfy any judgment against them, Plaintiffs expect that Defendant will produce any such agreement(s) for inspection or copying as required by Fed. R. Civ. P. 26(a)(1)(A)(iv).

Respectfully Submitted,

McCarter & English, LLP

/s/ Daniel M. Silver
Michael P. Kelly (# 2295)
Daniel M. Silver (# 4758)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
Tel.: (302) 984-6300
Fax: (302) 984-6399
mkelly@mccarter.com
dsilver@mccarter.com

Attorneys for Plaintiffs Genentech, Inc. and City of Hope

### OF COUNSEL:

Paul B. Gaffney David I. Berl Thomas S. Fletcher Teagan J. Gregory Jonathan S. Sidhu Williams & Connolly LLP 725 Twelfth St. NW Washington, DC 20005 (202) 434-5000

Attorneys for Plaintiff Genentech, Inc.

May 29, 2018

## Redacted in its Entirety

#### LAW OFFICES

### WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.

THOMAS FLETCHER (202) 434-5497 tfletcher@wc.com WASHINGTON, D. C. 20005-5901 (202) 434-5000 FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

December 10, 2018

### Via Email

Siegmund Gutman Proskauer Rose LLP 2049 Century Park East Los Angeles, CA 90067-3206

Re: Genentech v. Amgen, C.A. No. 17-1407 (CFC) (D. Del.) (consolidated)

Dear Sige:

In accordance with the Court's guidance at the hearing held on November 28, 2018, Plaintiffs hereby identify the following twenty-five asserted claims of the patents-in-suit:

US Patent No.	First Named Inventor	Asserted Claims
6,331,415	Cabilly	19, 20, 33
6,884,879	Baca	5, 6
7,060,269	Baca	2
7,169,901	Baca	6, 8
8,574,869	Kao	5, 8
9,795,672	Fyfe	1, 5, 6, 10, 15, 16, 18
8,512,983	Gawlitzek	2, 5, 6, 8, 9, 11, 19
9,441,035	Carvalhal	2

As to each of the patents-in-suit, Genentech has made the selection of asserted claims in reliance on the infringement and validity contentions provided by Amgen pursuant to 42 U.S.C.  $\S 262(l)(3)(B)$ , with the understanding that Amgen will not advance in litigation bases for non-infringement or invalidity that were not disclosed in its contentions. Were the Court to agree with Amgen's position that the contentions provided under  $\S (l)(3)$  are not binding, see D.I. 146 in C.A. No. 17-1407, Genentech reserves the right to assert claims not listed above.

### WILLIAMS & CONNOLLY LLP

December 10, 2018 Page 2

The Court's guidance of November 28, 2018 concerned the selection of claims from the Gawlitzek and Carvalhal patents. Genentech's selection of claims is informed by Amgen's production of samples from Amgen Rhode Island. It has not been informed by Amgen's production of samples from Amgen Thousand Oaks (which we understand were destroyed by Amgen rather than preserved), nor has it been informed by Amgen's production of batch records necessary to interpret the relevance of our analysis of Amgen's samples. Indeed, Amgen appears to have ignored Genentech's repeated requests for information of this nature, most recently my email of November 30. An informed selection of claims is not possible without such information, let alone a court-ordered selection that has any prospect of compliance with the Constitution. All of Plaintiffs' selections of patents and claims have been subject to, and without waiver of, its position that the Court's orders requiring narrowing are unconstitutional. *In re Katz Interactive Call Processing Pat. Litig.*, 639 F.3d 1303, 1312-13 & n.9 (Fed. Cir. 2011).

Genentech reserves the right to seek leave to modify its claim selections upon receipt and analysis of additional information.

Sincerely,

/s/

Thomas S. Fletcher

#### LAW OFFICES

### WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.

Thomas S. Fletcher (202) 434-5497 tfletcher@wc.com WASHINGTON, D. C. 20005-5901 (202) 434-5000 FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

January 4, 2019

### VIA EMAIL (gsirles@proskauer.com)

Gourdin W. Sirles, Esq. Proskauer LLP One International Place Boston, MA 02110-2600

Re: Genentech v. Amgen, C.A. No. 17-1407, 17-1471 (CFC) (D. Del.)

Dear Gourdin:

I write in response to your letter of December 17, 2018 concerning experimental testing.

Your letter appears to misapprehend the distinction between a consulting expert and a testifying expert. See generally Fed. R. Civ. P. 26(b)(4). If Genentech serves a report from an expert that it intends to call to testify about experimental testing, it will at that time produce the materials required by Rule 26(a)(2)(B). Until that time, however, whatever experimental testing that we have conducted in connection with this litigation is protected from disclosure.

I have reviewed the cases cited in your letter and, frankly, they reinforce the black letter law that I have explained above. The *Sandvik* case<sup>1</sup> acknowledges that the experimental testing at issue was protected by the attorney work product doctrine, but that the narrow exception to work product protection embodied in Rule 26(b)(3)(A)(ii) was met. The *Kimberly-Clark* case<sup>2</sup> also acknowledges that such testing is protected by the attorney work product doctrine and reflects the uncontroversial point that, to the extent a party relies upon such testing (for example, by serving an expert report), such materials must be produced. Finally, the *Union Carbide* case<sup>3</sup> that you quote at length and out of context is inapposite. It concerns the discoverability of internal documents that happen later to be forwarded to attorneys, which unsurprisingly are not protected. It does not speak to testing performed by a consulting expert.

If you would like to confer about this topic further, I am available Tuesday morning.

<sup>&</sup>lt;sup>1</sup> 2011 WL 466696 (W.D. Pa. Feb. 4, 2011).

<sup>&</sup>lt;sup>2</sup> 2010 WL 4537002 (M.D. Pa. Nov. 3, 2010).

<sup>&</sup>lt;sup>3</sup> 619 F. Supp. 1036 (D. Del. 1985).

## 

WILLIAMS & CONNOLLY LLP January 4, 2019 Page 2

Sincerely,

/s/

Thomas S. Fletcher

From: Ford, Katie <kford@mccarter.com>
Sent: Monday, February 25, 2019 4:43 PM

To: Naini, Amir A.; Anupa Smit; Hanna, David M.; Sirles, Gourdin W.; 'J. Higgins'; Mottley,

Kimberly A.; 'M. Sharp'; Mechelle Gassaway; Michelle Ovanesian; AmgenABP215;

Gutman, Siegmund Y.; Bauer, Steven M.

Cc: Adam Brausa; Smyth, Benjamin; 'D. Berl'; Silver, Daniel; Daralyn Durie; Eneda Hoxha; Eric

Wiener; 'J. Sidhu'; Joyce, Alexandra; K. Kayali; L. McCloud; Kelly, Michael P.; M. Reynolds; Moskowitz, Benjamin; 'P. Gaffney'; Rick Rosser; Sumeet Dang; 'T. Fletcher'; 'T. Gregory'

Subject: Genentech v. Amgen (Avastin), C.A. No. 17-1407-GMS

Attachments: DI 266 Genentech\_Amgen -- 20190225 NOD V. Vunnum.PDF; DI 265

Genentech\_Amgen -- 20190225 NOD J. Yant.PDF; DI 264 Genentech\_Amgen --

20190225 NOD A. Stambaugh.PDF

Counsel,

Attached please find the following documents as filed today.

### **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:37 PM EST and filed on 2/25/2019

Case Name:

Genentech, Inc. et al v. Amgen Inc.

Case Number:

1:17-cv-01407-CFC

Filer:

City of Hope

Genentech, Inc.

**Document Number: 264** 

**Docket Text:** 

NOTICE to Take Deposition of Angela Stambaugh on March 7, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

### **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:38 PM EST and filed on 2/25/2019

Case Name:

Genentech, Inc. et al v. Amgen Inc.

**Case Number:** 

1:17-cv-01407-CFC

Filer:

City of Hope

Genentech, Inc.

**Document Number: 265** 

**Docket Text:** 

NOTICE to Take Deposition of Jeffrey Yant on March 6, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

### **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:40 PM EST and filed on 2/25/2019

Case Name:

Genentech, Inc. et al v. Amgen Inc.

### Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 108 of 123 PageID #:

**Case Number:** 1:17-cv-01407-CFC

Filer: City of Hope

Genentech, Inc.

**Document Number: 266** 

**Docket Text:** 

NOTICE to Take Deposition of Venkata Vunnum on March 8, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

Thank you, Katie



Katie Ford | Paralegal McCARTER & ENGLISH, LLP

Renaissance Centre, 405 N. King Street, 8th Floor | Wilmington, Delaware 19801

T: 302-984-6332

kford@mccarter.com | www.mccarter.com

BOSTON | HARTFORD | STAMFORD | NEW YORK | NEWARK EAST BRUNSWICK | PHILADELPHIA | WILMINGTON | WASHINGTON, DC

Think Green! Please consider the impact on the environment before printing this e-mail.

This email message from the law firm of McCarter & English, LLP is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

# Exhibit 21

## Sirles, Gourdin W.

From: Fletcher, Thomas <TFletcher@wc.com>
Sent: Monday, February 25, 2019 4:50 PM

To: Ford, Katie; Naini, Amir A.; Anupa Smit; Hanna, David M.; Sirles, Gourdin W.; 'J.

Higgins'; Mottley, Kimberly A.; 'M. Sharp'; Mechelle Gassaway; Michelle Ovanesian ;

AmgenABP215; Gutman, Siegmund Y.; Bauer, Steven M.

Cc: Adam Brausa; Smyth, Benjamin; Berl, David; Silver, Daniel; Daralyn Durie; Eneda Hoxha;

Eric Wiener; Sidhu, Jonathan; Joyce, Alexandra; Kayali, Kathryn; McCloud, Luke; Kelly, Michael P.; Reynolds, Malcolm; Moskowitz, Benjamin; Gaffney, Paul; Rick Rosser; Dang,

Sumeet; Gregory, Teagan

Subject: RE: Genentech v. Amgen (Avastin), C.A. No. 17-1407-GMS

## Counsel,

In connection with these depositions, please advise whether you are authorized to accept service on behalf of these witnesses of subpoenas for these depositions. If we do not hear from you on this point by close of business tomorrow, we will begin making efforts to serve deposition subpoenas on the witnesses personally.

We remain amenable to scheduling these depositions at alternative dates and locations, as explained in my email of February 11 asking you to propose such alternative dates and locations. Having received no response to that email over the past two weeks, we have served the new deposition notices attached to the email below.

Regards,

Tom

Thomas S. Fletcher

Williams & Connolly LLP 725 Twelfth St. NW Washington, DC 20005 (202) 434-5497

From: Ford, Katie [mailto:kford@mccarter.com]
Sent: Monday, February 25, 2019 4:44 PM

**To:** Amir Naini <anaini@proskauer.com>; Anupa Smit <asmit@ycst.com>; David Hanna <dhanna@proskauer.com>; Gourdin Sirles <gsirles@proskauer.com>; 'J. Higgins' <jhiggins@ycst.com>; Kimberly Mottley

<kmottley@proskauer.com>; 'M. Sharp' <msharp@ycst.com>; Mechelle Gassaway <mgassaway@ycst.com>; Michelle Ovanesian <movanesian@ycst.com>; Proskauer Email <AmgenABP215@proskauer.com>; 'S. Gutman'

<sgutman@proskauer.com>; Steven Bauer <sbauer@proskauer.com>

Cc: Adam Brausa <abrausa@durietangri.com>; Smyth, Benjamin <bsmyth@McCarter.com>; Berl, David <DBerl@wc.com>; Silver, Daniel <DSilver@McCarter.com>; Daralyn Durie <ddurie@durietangri.com>; Eneda Hoxha <ehoxha@durietangri.com>; Eric Wiener <ewiener@durietangri.com>; Sidhu, Jonathan <JSidhu@wc.com>; Joyce, Alexandra <ajoyce@mccarter.com>; Kayali, Kathryn <KKayali@wc.com>; McCloud, Luke <LMcCloud@wc.com>; Kelly, Michael P. <MKelly@McCarter.com>; Reynolds, Malcolm <MReynolds@wc.com>; Moskowitz, Benjamin

## Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 111 of 123 PageID #: 26521

<BMoskowitz@wc.com>; Gaffney, Paul <PGaffney@wc.com>; Rick Rosser <RRosser@durietangri.com>; Dang, Sumeet <sdang@wc.com>; Fletcher, Thomas <TFletcher@wc.com>; Gregory, Teagan <TGregory@wc.com> Subject: Genentech v. Amgen (Avastin), C.A. No. 17-1407-GMS

Counsel,

Attached please find the following documents as filed today.

### **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:37 PM EST and filed on 2/25/2019

Case Name:

Genentech, Inc. et al v. Amgen Inc.

Case Number:

1:17-cv-01407-CFC

Filer:

City of Hope

Genentech, Inc.

**Document Number: 264** 

### **Docket Text:**

NOTICE to Take Deposition of Angela Stambaugh on March 7, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

### **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:38 PM EST and filed on 2/25/2019

**Case Name:** 

Genentech, Inc. et al v. Amgen Inc.

**Case Number:** 

1:17-cv-01407-CFC

Filer:

City of Hope

Genentech, Inc.

**Document Number: 265** 

#### **Docket Text:**

NOTICE to Take Deposition of Jeffrey Yant on March 6, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

#### **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:40 PM EST and filed on 2/25/2019

Case Name:

Genentech, Inc. et al v. Amgen Inc.

**Case Number:** 

1:17-cv-01407-CFC

Filer:

City of Hope

Genentech, Inc.

**Document Number: 266** 

#### **Docket Text:**

NOTICE to Take Deposition of Venkata Vunnum on March 8, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

Thank you,

Katie

## Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 112 of 123 PageID #: 26522



#### Katie Ford | Paralegal McCARTER & ENGLISH, LLP

Renaissance Centre, 405 N. King Street, 8th Floor | Wilmington, Delaware 19801 T: 302-984-6332 kford@mccarter.com | www.mccarter.com

BOSTON | HARTFORD | STAMFORD | NEW YORK | NEWARK EAST BRUNSWICK | PHILADELPHIA | WILMINGTON | WASHINGTON, DC

Think Green! Please consider the impact on the environment before printing this e-mail.

This email message from the law firm of McCarter & English, LLP is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

This message and any attachments are intended only for the addressee and may contain information that is privileged and confidential. If you have received this message in error, please do not read, use, copy, distribute, or disclose the contents of the message and any attachments. Instead, please delete the message and any attachments and notify the sender immediately. Thank you.

# Exhibit 22

# Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 114 of 123 PageID #: 26524

**From:** Sirles, Gourdin W.

**Sent:** Monday, March 4, 2019 9:23 AM

**To:** Fletcher, Thomas

Cc: Ford, Katie; Naini, Amir A.; Anupa Smit; Hanna, David M.; J. Higgins; Mottley, Kimberly

A.; M. Sharp; Mechelle Gassaway; Michelle Ovanesian; AmgenABP215; Gutman, Siegmund Y.; Bauer, Steven M.; Adam Brausa; Smyth, Benjamin; Berl, David; Silver, Daniel; Daralyn Durie; Eneda Hoxha; Eric Wiener; Sidhu, Jonathan; Joyce, Alexandra; Kayali, Kathryn; McCloud, Luke; Kelly, Michael P.; Reynolds, Malcolm; Moskowitz,

Benjamin; Gaffney, Paul; Rick Rosser; Dang, Sumeet; Gregory, Teagan

Subject: RE: Genentech v. Amgen (Avastin), C.A. No. 17-1407-GMS

**Categories:** You have been BCC'd or have received this message as part of an email group.

Tom,

As mentioned in my below email, Amgen has been looking into the availability of the witnesses Plaintiffs noticed for depositions last week. Below are available dates and workable deposition locations.

Jeff Yant: May 17 at Thousand Oaks or Westlake Village, CA

Angela Stambaugh: May 23 at Proskauer's Boston office

Suresh Vunnum: May 30 or 31 at Thousand Oaks or Westlake Village, CA

Please confirm that these dates and locations work for Plaintiffs and select either May 30 or 31 for Suresh Vunnum.

Regards, Gourdin

From: Sirles, Gourdin W. <gsirles@proskauer.com>

**Sent:** Tuesday, February 26, 2019 8:19 PM **To:** Fletcher, Thomas <TFletcher@wc.com>

Cc: Ford, Katie <kford@mccarter.com>; Naini, Amir A. <ANaini@proskauer.com>; Anupa Smit <asmit@ycst.com>; Hanna, David M. <DHanna@proskauer.com>; J. Higgins <jhiggins@ycst.com>; Mottley, Kimberly A. <kmottley@proskauer.com>; M. Sharp <msharp@ycst.com>; Mechelle Gassaway <mgassaway@ycst.com>; Michelle Ovanesian <movanesian@ycst.com>; AmgenABP215 <AmgenABP215@proskauer.com>; Gutman, Siegmund Y. <sgutman@proskauer.com>; Bauer, Steven M. <SBauer@proskauer.com>; Adam Brausa <abrausa@durietangri.com>; Smyth, Benjamin <bsmyth@mccarter.com>; Berl, David <DBerl@wc.com>; Silver, Daniel <DSilver@mccarter.com>; Daralyn Durie <ddurie@durietangri.com>; Eneda Hoxha <ehoxha@durietangri.com>; Eric Wiener <ewiener@durietangri.com>; Sidhu, Jonathan <JSidhu@wc.com>; Joyce, Alexandra <ajoyce@mccarter.com>; Kayali, Kathryn <KKayali@wc.com>; McCloud, Luke <LMcCloud@wc.com>; Kelly, Michael P. <MKelly@mccarter.com>; Reynolds, Malcolm <MReynolds@wc.com>; Moskowitz, Benjamin <BMoskowitz@wc.com>; Gaffney, Paul <PGaffney@wc.com>; Rick Rosser <RRosser@durietangri.com>; Dang, Sumeet <sdang@wc.com>; Gregory, Teagan

Subject: Re: Genentech v. Amgen (Avastin), C.A. No. 17-1407-GMS

Tom,

<TGregory@wc.com>

# Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 115 of 123 PageID #: 26525

We are authorized to accept service of the deposition notices. We will follow up with available dates.

Regards, Gourdin

On Feb 25, 2019, at 4:49 PM, Fletcher, Thomas < TFletcher@wc.com > wrote:

Counsel,

In connection with these depositions, please advise whether you are authorized to accept service on behalf of these witnesses of subpoenas for these depositions. If we do not hear from you on this point by close of business tomorrow, we will begin making efforts to serve deposition subpoenas on the witnesses personally.

We remain amenable to scheduling these depositions at alternative dates and locations, as explained in my email of February 11 asking you to propose such alternative dates and locations. Having received no response to that email over the past two weeks, we have served the new deposition notices attached to the email below.

Regards,

Tom

Thomas S. Fletcher Williams & Connolly LLP 725 Twelfth St. NW Washington, DC 20005 (202) 434-5497

From: Ford, Katie [mailto:kford@mccarter.com]

Sent: Monday, February 25, 2019 4:44 PM

To: Amir Naini <anaini@proskauer.com>; Anupa Smit <asmit@ycst.com>; David Hanna <a href="mailto:dhanna@proskauer.com">dhanna@proskauer.com</a>; Gourdin Sirles <a href="mailto:gsirles@proskauer.com">gsirles@proskauer.com</a>; 'J. Higgins' <a href="mailto:jhiggins@ycst.com">jhiggins@ycst.com</a>; Kimberly Mottley <a href="mailto:kmottley@proskauer.com">kmottley@proskauer.com</a>; 'M. Sharp' <a href="mailto:msharp@ycst.com">msharp@ycst.com</a>; Mechelle Gassaway <a href="mailto:msharp@ycst.com">msharp@ycst.com</a>; Proskauer Email <a href="mailto:AmgenABP215@proskauer.com">amgenABP215@proskauer.com</a>; 'S. Gutman' <a href="mailto:sgutman@proskauer.com">sgutman@proskauer.com</a>; Steven Bauer <a href="mailto:sgutman@proskauer.com">sbauer@proskauer.com</a>; Steven Bauer

Cc: Adam Brausa <a href="mailto:abrausa@durietangri.com">abrausa@durietangri.com</a>; Smyth, Benjamin <a href="mailto:bsmyth@McCarter.com">bsmyth@McCarter.com</a>; Berl, David <a href="mailto:Dsilver@McCarter.com">abrause abrausa@durietangri.com</a>; Berl, David <a href="mailto:Dsilver@McCarter.com">abrause abrause a

Counsel,

Attached please find the following documents as filed today.

#### **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:37 PM EST and filed on 2/25/2019

Case Name:

Genentech, Inc. et al v. Amgen Inc.

**Case Number:** 

1:17-cv-01407-CFC

Filer:

City of Hope

Genentech, Inc.

**Document Number: 264** 

#### **Docket Text:**

NOTICE to Take Deposition of Angela Stambaugh on March 7, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

## Notice of Electronic Filing

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:38 PM EST and filed on 2/25/2019

Case Name:

Genentech, Inc. et al v. Amgen Inc.

**Case Number:** 

1:17-cv-01407-CFC

Filer:

City of Hope

Genentech, Inc.

**Document Number: 265** 

#### **Docket Text:**

NOTICE to Take Deposition of Jeffrey Yant on March 6, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

#### **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:40 PM EST and filed on 2/25/2019

Case Name:

Genentech, Inc. et al v. Amgen Inc.

**Case Number:** 

1:17-cv-01407-CFC

Filer:

City of Hope

Genentech, Inc.

**Document Number: 266** 

#### **Docket Text:**

NOTICE to Take Deposition of Venkata Vunnum on March 8, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

Thank you,

Katie

# Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 117 of 123 PageID #: 26527

<image001.jpg> Katie Ford | Paralegal
McCARTER & ENGLISH, LLP

Renaissance Centre, 405 N. King Street, 8th Floor | Wilmington, Delaware 19801 T: 302-984-6332 kford@mccarter.com | www.mccarter.com

BOSTON | HARTFORD | STAMFORD | NEW YORK | NEWARK EAST BRUNSWICK | PHILADELPHIA | WILMINGTON | WASHINGTON, DC

Think Green! Please consider the impact on the environment before printing this e-mail.

This email message from the law firm of McCarter & English, LLP is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

This message and any attachments are intended only for the addressee and may contain information that is privileged and confidential. If you have received this message in error, please do not read, use, copy, distribute, or disclose the contents of the message and any attachments. Instead, please delete the message and any attachments and notify the sender immediately. Thank you.

# Exhibit 23

## Sirles, Gourdin W.

From: Sent: Fletcher, Thomas <TFletcher@wc.com> Monday, March 4, 2019 11:47 AM

To:

Sirles, Gourdin W.

Cc:

Ford, Katie; Naini, Amir A.; Anupa Smit; Hanna, David M.; J. Higgins; Mottley, Kimberly A.; M. Sharp; Mechelle Gassaway; Michelle Ovanesian; AmgenABP215; Gutman, Siegmund Y.; Bauer, Steven M.; Adam Brausa; Smyth, Benjamin; Berl, David; Silver, Daniel; Daralyn Durie; Eneda Hoxha; Eric Wiener; Sidhu, Jonathan; Joyce, Alexandra; Kayali, Kathryn; McCloud, Luke; Kelly, Michael P.; Reynolds, Malcolm; Gaffney, Paul; Rick

Rosser; Dang, Sumeet; Gregory, Teagan; Genentech-Bevacizumab

**Subject:** 

RE: Genentech v. Amgen (Avastin), C.A. No. 17-1407-GMS

## Gourdin,

Your proposed alternatives are unacceptable. We reached out to you about scheduling these depositions in January. We withdrew notices for their depositions in February because you indicated the dates would not work, but you never proposed alternative dates. Accordingly, we re-noticed the depositions for March. We remain open to reasonable accommodations, but we cannot postpone this discovery by another two-and-a-half months given the scope of discovery in this case.

Please give me a call by close of business today to discuss alternatives for these depositions in March. Otherwise, we will expect Mr. Yant to honor his subpoena and appear on Wednesday morning and for Ms. Stambaugh and Mr. Vennum to do likewise later this week.

Regards,

Tom

Thomas S. Fletcher

Williams & Connolly LLP 725 Twelfth St. NW Washington, DC 20005 (202) 434-5497

From: Sirles, Gourdin W. [mailto:gsirles@proskauer.com]

Sent: Monday, March 04, 2019 9:23 AM
To: Fletcher, Thomas <TFletcher@wc.com>

Cc: Ford, Katie < kford@mccarter.com>; Naini, Amir A. < ANaini@proskauer.com>; Anupa Smit < asmit@ycst.com>; Hanna, David M. < DHanna@proskauer.com>; J. Higgins < jhiggins@ycst.com>; Mottley, Kimberly A. < kmottley@proskauer.com>; M. Sharp < msharp@ycst.com>; Mechelle Gassaway < mgassaway@ycst.com>; Michelle Ovanesian < movanesian@ycst.com>; AmgenABP215 < AmgenABP215@proskauer.com>; Gutman, Siegmund Y. < sgutman@proskauer.com>; Bauer, Steven M. < SBauer@proskauer.com>; Adam Brausa < abrausa@durietangri.com>; Smyth, Benjamin < bsmyth@mccarter.com>; Berl, David < DBerl@wc.com>; Silver, Daniel < DSilver@mccarter.com>; Daralyn Durie < ddurie@durietangri.com>; Eneda Hoxha < ehoxha@durietangri.com>; Eric Wiener

# Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 120 of 123 PageID #: 26530

<ewiener@durietangri.com>; Sidhu, Jonathan <JSidhu@wc.com>; Joyce, Alexandra <ajoyce@mccarter.com>; Kayali, Kathryn <KKayali@wc.com>; McCloud, Luke <LMcCloud@wc.com>; Kelly, Michael P. <MKelly@mccarter.com>; Reynolds, Malcolm <MReynolds@wc.com>; zzMoskowitz, Benjamin <BMoskowitz@wc.com>; Gaffney, Paul <PGaffney@wc.com>; Rick Rosser <RRosser@durietangri.com>; Dang, Sumeet <sdang@wc.com>; Gregory, Teagan <TGregory@wc.com>

Subject: RE: Genentech v. Amgen (Avastin), C.A. No. 17-1407-GMS

Tom,

As mentioned in my below email, Amgen has been looking into the availability of the witnesses Plaintiffs noticed for depositions last week. Below are available dates and workable deposition locations.

Jeff Yant: May 17 at Thousand Oaks or Westlake Village, CA

Angela Stambaugh: May 23 at Proskauer's Boston office

Suresh Vunnum: May 30 or 31 at Thousand Oaks or Westlake Village, CA

Please confirm that these dates and locations work for Plaintiffs and select either May 30 or 31 for Suresh Vunnum.

Regards, Gourdin

From: Sirles, Gourdin W. <gsirles@proskauer.com>

**Sent:** Tuesday, February 26, 2019 8:19 PM **To:** Fletcher, Thomas <TFletcher@wc.com>

Cc: Ford, Katie < kford@mccarter.com >; Naini, Amir A. < ANaini@proskauer.com >; Anupa Smit < asmit@ycst.com >; Hanna, David M. < DHanna@proskauer.com >; J. Higgins < iniggins@ycst.com >; Mottley, Kimberly A. < kmottley@proskauer.com >; M. Sharp < msharp@ycst.com >; Mechelle Gassaway < mgassaway@ycst.com >; Michelle Ovanesian < movanesian@ycst.com >; AmgenABP215 < AmgenABP215@proskauer.com >; Gutman, Siegmund Y. < sgutman@proskauer.com >; Bauer, Steven M. < SBauer@proskauer.com >; Adam Brausa < abrausa@durietangri.com >; Smyth, Benjamin < bsmyth@mccarter.com >; Berl, David < DBerl@wc.com >; Silver, Daniel < DSilver@mccarter.com >; Daralyn Durie < ddurie@durietangri.com >; Eneda Hoxha < ehoxha@durietangri.com >; Eric Wiener < ewiener@durietangri.com >; Sidhu, Jonathan < JSidhu@wc.com >; Joyce, Alexandra < ajoyce@mccarter.com >; Kayali, Kathryn < KKayali@wc.com >; McCloud, Luke < LMcCloud@wc.com >; Kelly, Michael P. < MKelly@mccarter.com >; Reynolds, Malcolm < MReynolds@wc.com >; Moskowitz, Benjamin < BMoskowitz@wc.com >; Gaffney, Paul < PGaffney@wc.com >; Rick Rosser < RRosser@durietangri.com >; Dang, Sumeet < sdang@wc.com >; Gregory, Teagan < TGregory@wc.com >

Subject: Re: Genentech v. Amgen (Avastin), C.A. No. 17-1407-GMS

Tom,

We are authorized to accept service of the deposition notices. We will follow up with available dates.

Regards, Gourdin

On Feb 25, 2019, at 4:49 PM, Fletcher, Thomas < TFletcher@wc.com > wrote:

Counsel,

# Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 121 of 123 PageID #: 26531

In connection with these depositions, please advise whether you are authorized to accept service on behalf of these witnesses of subpoenas for these depositions. If we do not hear from you on this point by close of business tomorrow, we will begin making efforts to serve deposition subpoenas on the witnesses personally.

We remain amenable to scheduling these depositions at alternative dates and locations, as explained in my email of February 11 asking you to propose such alternative dates and locations. Having received no response to that email over the past two weeks, we have served the new deposition notices attached to the email below.

Regards,

Tom

Thomas S. Fletcher

Williams & Connolly LLP 725 Twelfth St. NW Washington, DC 20005 (202) 434-5497

From: Ford, Katie [mailto:kford@mccarter.com]
Sent: Monday, February 25, 2019 4:44 PM

To: Amir Naini <anaini@proskauer.com>; Anupa Smit <asmit@ycst.com>; David Hanna <a href="mailto:dhanna@proskauer.com">dhanna@proskauer.com</a>; Gourdin Sirles <a href="mailto:gsirles@proskauer.com">gsirles@proskauer.com</a>; J. Higgins <a href="mailto:higgins@ycst.com">jhiggins@ycst.com</a>; Kimberly Mottley <a href="mailto:kmottley@proskauer.com">kmottley@proskauer.com</a>; M. Sharp' <a href="mailto:msasaway@ycst.com">msharp@ycst.com</a>; Mechelle Gassaway <a href="mailto:msasaway@ycst.com">msharp@ycst.com</a>; Proskauer Email <a href="mailto:AmgenABP215@proskauer.com">amgenABP215@proskauer.com</a>; 'S. Gutman' <a href="mailto:sgutman@proskauer.com">sgutman@proskauer.com</a>; Steven Bauer <a href="mailto:sgutman@proskauer.com">sbauer@proskauer.com</a>; Steven Bauer

Cc: Adam Brausa <a href="mailto:com">abrausa@durietangri.com">abrausa@durietangri.com</a>; Smyth, Benjamin <a href="mailto:bsmyth@McCarter.com">bsmyth@McCarter.com</a>; Berl, David <a href="mailto:DSilver@McCarter.com">abrause.com</a>; Silver, Daniel <a href="mailto:DSilver@McCarter.com">Daralyn Durie <a href="mailto:ddurie@durietangri.com">adurie@durietangri.com</a>; Eric Wiener <a href="mailto:ewiener@durietangri.com">ewiener@durietangri.com</a>; Sidhu, Jonathan <a href="mailto:JSidhu@wc.com">Sidhu, Jonathan <a href="mailto:JSidhu@wc.com">sidhu@wc.com</a>; Kayali, Kathryn <a href="mailto:KKayali@wc.com">KKayali@wc.com</a>; McCloud, Luke <a href="mailto:LMcCloud@wc.com">LMcCloud@wc.com</a>; Kelly, Michael P. <a href="mailto:AMkelly@McCarter.com">Mkelly@McCarter.com</a>; Reynolds, Malcolm <a href="mailto:MReynolds@wc.com">MReynolds@wc.com</a>; Benjamin <a href="mailto:BMoskowitz@wc.com">BMoskowitz@wc.com</a>; Gaffney, Paul <a href="mailto:PGaffney@wc.com">PGaffney@wc.com</a>; Rick Rosser <a href="mailto:RRosser@durietangri.com">RRosser@durietangri.com</a>; Dang, Sumeet <a href="mailto:sdang@wc.com">sdang@wc.com</a>; Fletcher@wc.com</a>; Gregory, Teagan <a href="mailto:TGregory@wc.com">TGregory@wc.com</a>>
<a href="mailto:Sdang@wc.com">Subject: Genentech v. Amgen (Avastin), C.A. No. 17-1407-GMS</a>

Counsel,

Attached please find the following documents as filed today.

## **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:37 PM EST and filed on 2/25/2019

**Case Name:** 

Genentech, Inc. et al v. Amgen Inc.

**Case Number:** 

1:17-cv-01407-CFC

# Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 122 of 123 PageID #:

Filer:

City of Hope

Genentech, Inc.

**Document Number: 264** 

**Docket Text:** 

NOTICE to Take Deposition of Angela Stambaugh on March 7, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

## **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:38 PM EST and filed on 2/25/2019

Case Name:

Genentech, Inc. et al v. Amgen Inc.

Case Number:

1:17-cv-01407-CFC

Filer:

City of Hope

Genentech, Inc.

**Document Number: 265** 

**Docket Text:** 

NOTICE to Take Deposition of Jeffrey Yant on March 6, 2019 filed by City of Hope, Genentech, Inc..(Silver, Daniel)

## **Notice of Electronic Filing**

The following transaction was entered by Silver, Daniel on 2/25/2019 at 4:40 PM EST and filed on 2/25/2019

Case Name:

Genentech, Inc. et al v. Amgen Inc.

**Case Number:** 

1:17-cv-01407-CFC

Filer:

City of Hope

Genentech, Inc.

**Document Number: 266** 

#### **Docket Text:**

NOTICE to Take Deposition of Venkata Vunnum on March 8, 2019 filed by City of Hope, Genentech, Inc. (Silver, Daniel)

Thank you, Katie

<image001.jpg> Katie Ford | Paralegal McCARTER & ENGLISH, LLP

> Renaissance Centre, 405 N. King Street, 8th Floor | Wilmington, Delaware 19801 T: 302-984-6332

kford@mccarter.com | www.mccarter.com

BOSTON | HARTFORD | STAMFORD | NEW YORK | NEWARK EAST BRUNSWICK | PHILADELPHIA | WILMINGTON | WASHINGTON, DC

Think Green! Please consider the impact on the environment before printing this e-mail.

# Case 1:17-cv-01407-CFC-SRF Document 302 Filed 03/15/19 Page 123 of 123 PageID #: 26533

This email message from the law firm of McCarter & English, LLP is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

This message and any attachments are intended only for the addressee and may contain information that is privileged and confidential. If you have received this message in error, please do not read, use, copy, distribute, or disclose the contents of the message and any attachments. Instead, please delete the message and any attachments and notify the sender immediately. Thank you.

This message and its attachments are sent from a law firm and may contain information that is confidential and protected by privilege from disclosure.

If you are not the intended recipient, you are prohibited from printing, copying, forwarding or saving them. Please delete the message and attachments without printing, copying, forwarding or saving them, and notify the sender immediately.

\*

\*